EPA Registration #1448-433

Volume 2

Fee for Service {962927G~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 31

Receipt No. S- 962927

EPA File Symbol/Reg. No. 1448-433

Pin-Punch Date: 1/15/2015

☑ This item is NOT subject to FFS action.

Action Code:

Requested: —

Granted:

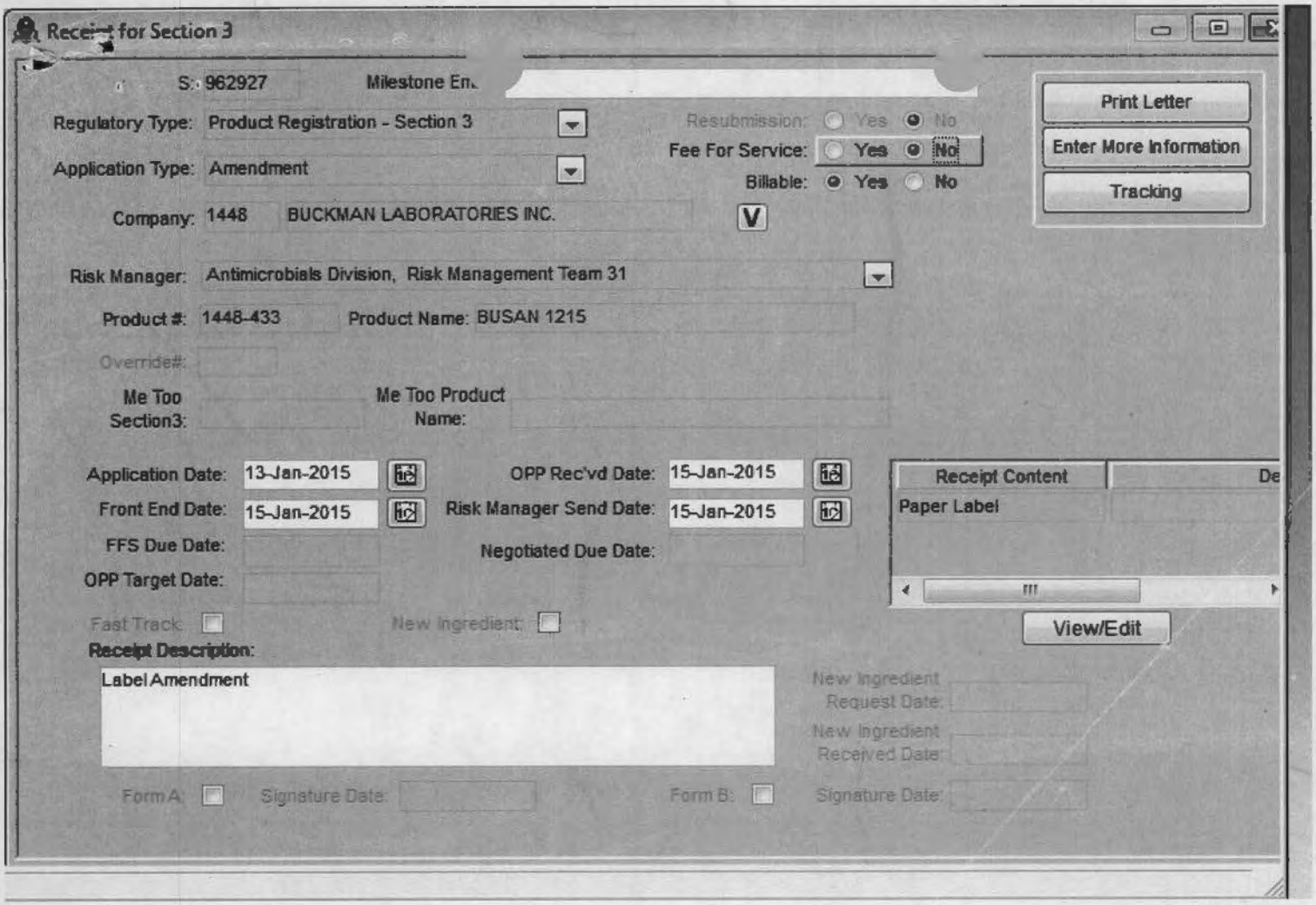
Amount Due: $ -0-

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Mail Code Team1 Date: 1/15/15

Remarks:


Receipt for Section 3
S: 962927
Milestone En
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 1448 BUCKMAN LABORATORIES INC.
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 1448-433
Product Name: BUSAN 1215
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 13-Jan-2015
OPP Rec'vd Date: 15-Jan-2015
Front End Date: 15-Jan-2015
Risk Manager Send Date: 15-Jan-2015
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
De
Paper Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Label Amendment
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

C labels

A1.1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 15, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JEFFREY M. THORNE
BUCKMAN LABORATORIES INC.
1256 NORTH MCLEAN BLVD
MEMPHIS, TN 38108

PRODUCT NAME: BUSAN 1215
COMPANY NAME: BUCKMAN LABORATORIES INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 1448-433
EPA RECEIPT DATE: 01/15/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

Francine Morris

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448-433	Velma Noble	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
BUSAN 1215	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Amendment: Non-PRIA action.
ACTION: Revise the Directions for Use to add "Not registered for mollusk control in California" to Industrial Water Systems. Please note that this is a correction from the letter dated 6 January 2015.

Contact: cwbrown@buckman.com; FAX: (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Crystal W. Brown, MS	Sr. Regulatory Affairs Specialist	(901) 272-8258

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
	Sr. Regulatory Affairs Specialist	
4. Typed Name	**5. Date**	
Crystal W. Brown, MS	13 January 2015	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new product registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Buckman
NORTH AMERICA

Buckman Lab[illegible]s, Inc.
1256 North Mc[illegible]n Blvd.
Memphis, TN 38108-1241 USA

(901) 278-0330 Tel
(901) 276-5343 Fax
buckman.com

via Federal Express

13 January 2015

Ms. Velma Noble, PM 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22203-4501

Re: Label Amendment – Not registered for use in California.
EPA Registration Number: 1448-433
Correction from 6 January 2015 dated letter

Dear Ms. Noble:

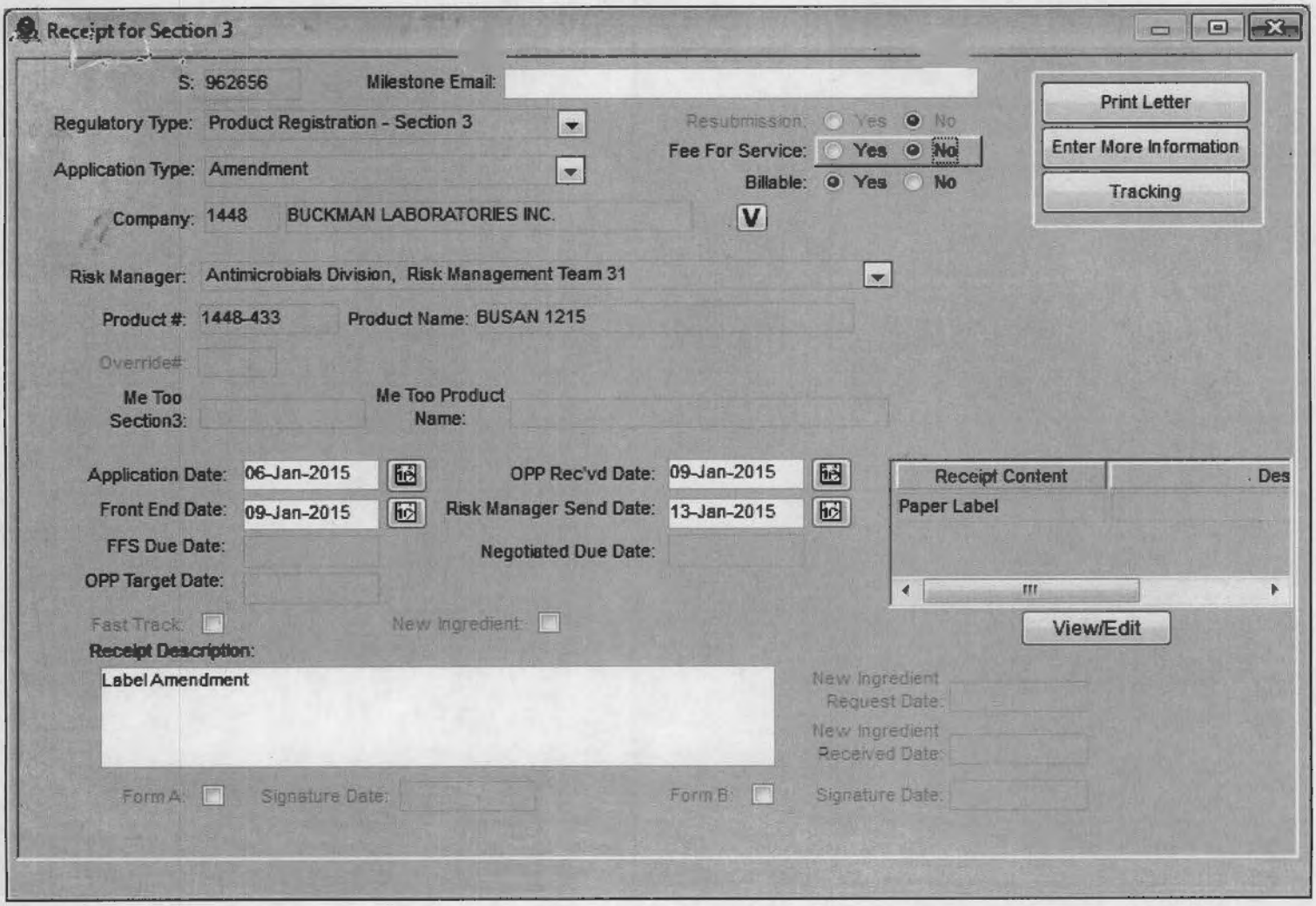
Buckman Laboratories submits the following label amendment for the product, BUSAN 1215 (EPA Reg. # 1448-433), to revise Directions for Use under Industrial Water System to add "Not registered for mollusk control in California." Please cancel the 6 January 2015 submission which merely stated, "Not registered for use in California."

Please find enclosed the EPA application Form 8570-1 and 5 copies of the draft revised labels incorporating the above referenced changes. Should you have any questions or require additional information, please contact me at (901) 272-8258 (cwbrown@buckman.com).

Sincerely,

BUCKMAN LABORATORIES INTERNATIONAL, INC.

Crystal W. Brown, MS
Sr. Regulatory Affairs Specialist


Receipt for Section 3
S: 962656
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 1448 BUCKMAN LABORATORIES INC.
V
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 1448-433
Product Name: BUSAN 1215
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 06-Jan-2015
OPP Rec'vd Date: 09-Jan-2015
Front End Date: 09-Jan-2015
Risk Manager Send Date: 13-Jan-2015
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Paper Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Label Amendment
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

cletus

Fee for Service {962656D~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 31

Receipt No. S- 962656

EPA File Symbol/Reg. No. 1448-433

Pin-Punch Date: 1/9/2015

☑ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Team 1 Date: 1-12-15

Remarks:

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448-433	Velma Noble	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
BUSAN 1215	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Amendment: Non-PRIA action.
ACTION: Revise the Directions for Use to add Not registered for use in California to Industrial Water Systems.

Contact: cwbrown@buckman.com; FAX: (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

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Section - IV

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Name	Title	Telephone No. (Include Area Code)
Crystal W. Brown, MS	Sr. Regulatory Affairs Specialist	(901) 272-8256

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	5. Date
	Sr. Regulatory Affairs Specialist	6 January 2015
4. Typed Name: Crystal W. Brown, MS		

EPA Form 6570-1 (Rev. 3-94) Previous editions a. ...olete. White - EPA File Copy (original) Yellow - Applicant Copy

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Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

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2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

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2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Buckman
NORTH AMERICA

Buckman Laboratories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108-1241 USA

(901) 278-0330 Tel
(901) 276-5343 Fax
buckman.com

via Federal Express

6 January 2015

Ms. Velma Noble, PM 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22203-4501

Re: Label Amendment – Not registered for use in California.
EPA Registration Number: 1448-433

Dear Ms. Noble:

Buckman Laboratories submits the following label amendment for the product, BUSAN 1215 (EPA Reg. # 1448-433), to revise Directions for Use under Industrial Water System to add "Not registered for use in California."

Please find enclosed the EPA application Form 8570-1 and 5 copies of the draft revised labels incorporating the above referenced changes. Should you have any questions or require additional information, please contact me at (901) 272-8258 (cwbrown@buckman.com).

Sincerely,

BUCKMAN LABORATORIES INTERNATIONAL, INC.

Crystal W. Brown, MS
Sr. Regulatory Affairs Specialist

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 13, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JEFFREY M. THORNE
BUCKMAN LABORATORIES INC.
1256 NORTH MCLEAN BLVD
MEMPHIS, TN 38108

PRODUCT NAME: BUSAN 1215
COMPANY NAME: BUCKMAN LABORATORIES INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 1448-433
EPA RECEIPT DATE: 01/09/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

Francine Tomlin

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 30, 2011

Buckman Laboratories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108-1241

ATTN: Dennis L. Barbee

NOTIFICATION OF FINAL PRINTED LABEL:

1448-283	1448-282	1448-277	1448-243	1448-243	1448-399
1448-395	1448-394	1448-388	1448-382	1448-381	1448-375
1448-374	1448-377	1448-376	1448-371	1448-363	1448-360
1448-359	1448-358	1448-357	1448-354	1448-351	1448-345
1448-339	1448-338	1448-337	1448-433	1448-432	1448-428
1448-427	1448-423	1448-422	1448-421	1448-412	

The submitted final printed labels have been placed in your product file. In accordance with PR Notice 82-2 the labels have not been reviewed.

If you have any questions concerning this letter, please contact Marshall Swindell at (703) 308-6341.

Sincerely yours,

Marshall Swindell

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Buckman
USA

Buckman La ories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108-1241 USA

(901) 278-0330 Tel
(901) 276-5343 Fax
buckman.com

18 March 2011

Marshall Swindell
Product Manager (33)
US EPA, OPP, AD, RMB I (7510P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: BUSAN 1215
EPA Reg. No. 1448-433
Label Revision

Please find enclosed a copy of the revised printed label containing comments received in the EPA letter dated, January 7, 2011.

If you have any questions or require any additional information regarding this submission, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448-433	Marshall Swindell	[ ] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
BUSAN 1215	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [x] Resubmission in response to Agency letter dated Jan 7, 2011
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Amendment: Non-PRIA action.
ACTION: Revised per comments.

Contact: cfwatson@buckman.com; FAX: (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watson	Sr. Regulatory Toxicologist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Carl F Wat	Sr. Regulatory Toxicologist
4. Typed Name	**5. Date**
Carl F. Watson, Ph.D.	18 March 2011

BUSAN 1215

BUSAN is a registered trademark.

Buckman

ACTIVE INGREDIENT(S)	
Ammonia (total)	7.59%
INERT INGREDIENTS	92. 41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-767-2722 for emergency medical treatment information.

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: The pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NOT REVIEWED
In accordance with PR Notice 88-8.
Based on Draft Labeling Dated 3/30/11

BUSAN 1215

BUSAN is a registered trademark.

Buckman

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MILLS: BUSAN 1215 is used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems must be cleaned before initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

INDUSTRIAL WATER SYSTEMS: BUSAN 1215 is used for the control of algal, bacterial and fungal deposits in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

When this product is used to treat sewage and wastewater systems, seawater, and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, and the system water is not sent to a POTW; residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment.

When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes; effluent detection of chloramine should be conducted at least once per shift. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water process through a closed metered chemical feed system. The system operator must be trained by a Buckman representative in the use of the chemical feed system. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems must be cleaned before initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems must be cleaned before initial treatment.

BUSAN 1215

Buckman

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products and in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources. .

Nonrefillable

5 gals or less

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for the later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If metal container, do not puncture or burn.

Capacity of >5 gals

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use of disposal. Repeat this procedure two more times. Then offer for recycling if available or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If metal container, do not puncture or burn.

Refillable

Larger than 55 gallons

CONTAINER HANDLING: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to refilling or disposal, use a pressure wash as follows: Empty the remaining contents into application equipment or a mix tank. Use a pressure wash system that rinses all interior sides with water and that is rated at >40 psi and >120F. Pressure wash the container for a length of time that ensures that a minimum 25% of the container volume of water is used. During the pressure wash, ensure that the container valve is left open for continuous draining. Collect the rinsate and empty into application equipment or a mix tank or store rinsate for later use or disposal. Allow container to drain for 10 minutes after pressure wash is completed.

55 gallons and smaller

CONTAINER HANDLING: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to refilling or disposal, use a triple rinse wash as follows: Empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously. Pour or pump rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this rinsing procedure two more times.

Manufactured by **Buckman Laboratories, Inc.**
1256 North McLean Blvd., Memphis, Tennessee 38108, USA
(901) 278-0330 or 1-800-282-5626

EPA Est. No. 1448-TN-1

EPA Reg. No. 1448-433

Product Weight 9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health 1 Flammability 1 Reactivity 0

Last Revision

3/10/2011

Material to be added to an e-Jacket/Jacket

Reg. No. 1448-433

1. ☑ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

   _____

   _____

2. ☐ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☐ Notification
   - ☐ New CSF
   - ☑ Other: Amendment

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: A. Downs

Phone: _____ Division: AD

Date: 1/7/11

Created July 21/2008

DECISION PKG. NO. 443195 SUBM. DUE DATE 2/28/11

SUBMISSION BAR CODE # 887339 REVIEWER AD.

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMEI

FILE SYMBOL/REG NO. 1448-433 PM 33 ACTION CODE 302 PRIA

DESCRIPTOR Amendment FQPA NFQPA

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED US

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
11/30/10	11/30/10	11/30/10

METHOD OF SUPPORT

[ ] CITE-ALL [ ] SELECTIVE
[ ] NOT SUBMITTED [ ] N/A

FORMULATORS EXEMPTION

[ ] SUBMITTED [ ] NOT SUBMITTED
[ ] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER:				

STATUS

RESPONSE CODE 1155 RESPONSE DATE 1/7/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Buckman Laboratories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108-1241 USA

JAN 07 2011

Attention: Jeffery M. Thorne
Director, Compliance

Subject: Busan 1215
EPA Reg. No.: 1448-433
Amendment Application Dated: November 30, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency approves the following changes made to the label:

- Revise the Container Size as follows:
  - 1, 3.5, 5, 15, 30, 20, 35, 55, 125, 275, 330, 400 gallons and bulk.

Please note that different container sizes have different storage and disposal requirements. The label must be amended to include these requirements.

Review of this product has revealed several label deficiencies. Update your label according to the following directions and submit a new label to the Agency for review within 30 days of this letter.

1. Revise the Hazards to Humans and Domestic Animals section to include the phrase:

   "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse."

2. Revise the Environmental Hazards section to include the phrase, "This pesticide is toxic to fish and aquatic organisms."

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,

Abigail T. Downs
for

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Please read instructions on reverse before completing form. Form Approved. No. 2070-0060 Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
Buckman Laboratories, Inc. / 1448-433

2. EPA Product Manager
M. Swindell

3. Proposed Classification
[X] None [ ] Restricted

4. Company/Product (Name)
Buckman Laboratories, Inc. / Busan 1215

PM#
33

5. Name and Address of Applicant *(Include ZIP Code)*
Buckman Laboratories, Inc
1256 N. McLean Blvd.
Memphis, TN 38108
[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revise container sizes for this product

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging
[ ] Yes*
[X] No
** Certification must be submitted*

Unit Packaging
[ ] Yes
[X] No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging
[ ] Yes
[X] No
If "Yes" Package wgt / No. per container

2. Type of Container
[X] Metal
[X] Plastic
[ ] Glass
[ ] Paper
[ ] Other (Specify) _____

3. Location of Net Contents Information
[ ] Label [X] Container

4. Size(s) Retail Container
See Attachment

5. Location of Label Directions
[X] On Label
[ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
[X] Lithograph
[ ] Paper glued
[ ] Stenciled
[ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Jeffery M. Thorne	Director, Compliance	901.278.0330

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature J. M. Thorne

3. Title
Director, Compliance

4. Typed Name
Jeffery M. Thorne

5. Date
11/30/10

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

ATTACHMENT FOR

Buckman Laboratories, Inc.
EPA Registration No.: 1448-433
Product Name: Busan 1215

Section II (Continued)

Container Sizes: (1, 3.5, 5, 15, 30, 20, 35, 55, 125, 275, 330, 400) gallons & bulk

Material to be added to an e-Jacket/Jacket

Reg. No. 1448-433

1. ☐ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

_____

_____

2. ☒ **Send to Data Extraction contractors this material:**
   - ☒ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: D Copeland

Phone: _____ **Division:** AD

Date: _____

Created January 26, 2009

JUN 14 2010

Mr. Carl F. Watason, Ph.D.
Senior Regulatory Toxicologist
Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis TN 38108

Subject: **BUSAN 1215**
EPA Registration Number 1448-433
Application Dated March 16, 2010
EPA Received Date March 17, 2010

Dear Mr. Watson:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following.

Proposed Amendment:

- Revise the Storage & Disposal Section PR Notice 2007-4

General Comments:

Revise label as follows:

1.) Revise the "Container Disposal" heading on page 2 to read "Container *Handling*."

2.) The nonrefillable container text must be consolidated for clarity by stating the following:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) and promptly after emptying. Then offer for recycling or reconditioning, if available. If not, puncture and dispose of in sanitary landfill, or if allowed by state and local authorities by burning. If burned, stay out of smoke. If metal container, do not puncture or burn.

(Residue Removal for <5 gallons): Proposed Language is acceptable.
(Residue Removal for > 5 gallons): Proposed Language is acceptable.

CONCURRENCE							
SYMBOL							
SURNAME							
DATE							

3.) Delete the last three statements under "Storage and Disposal" because they are repetitive. These statements are the Environmental Hazards statements which already appear on page 1.

4.) The last statement under the "For Intermittent and Continuous Treatment" directions for both Pulp and Paper Mills and Industrial Water System on page 3 must be revised to be in compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should and stating "*must.*"

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Drusilla Copeland

for Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: stamped label

BUSAN 1215

BUSAN is a registered trademark.

Buckman

ACTIVE INGREDIENT(S)	
Ammonia (total)	7.59%
INERT INGREDIENTS	92. 41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-767-2722 for emergency medical treatment information.

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUN 14 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1448-433

BUSAN 1215

Buckman

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products and in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources. .

CONTAINER DISPOSAL:
(Text for all nonrefillable containers}
Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. **Plastic Containers**: May be incinerated, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. **Metal Containers**: Must not be incinerated. Do not cut or weld on or near metal containers.
{Liquid residue removal statement for nonrefillable containers with capacity of 5 gals or less}
Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for the later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.
{Liquid residue removal statement for nonrefillable containers with capacity of >5 gals}
Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use of disposal. Repeat this procedure two more times.
(Text for all nonrefillable containers)
Then offer for recycling if available or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities by burning. If burned, stay out of smoke.
{Text for refillable containers}
Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.
For containers larger than 55 gallons:
To clean the container prior to refilling or disposal, use a pressure wash as follows: Empty the remaining contents into application equipment or a mix tank. Use a pressure wash system that rinses all interior sides with water and that is rated at >40 psi and >120F. Pressure wash the container for a length of time that ensures that a minimum 25% of the container volume of water is used. During the pressure wash, ensure that the container valve is left open for continuous draining. Collect the rinsate and empty into application equipment or a mix tank or store rinsate for later use or disposal. Allow container to drain for 10 minutes after pressure wash is completed.
For containers 55 gallons and smaller:
To clean the container prior to refilling or disposal, use a triple rinse wash as follows: Empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously. Pour or pump rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this rinsing procedure two more times.
Do not discharge rinsate containing this product unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge rinsate containing this product to sewer systems without prior approval from the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Batch code: _____

Manufactured by **Buckman Laboratories, Inc.**
1256 North McLean Blvd., Memphis, Tennessee 38108, USA
(901) 278-0330 or 1-800-282-5626

EPA Est. No. 1448-TN-1

EPA Reg. No. 1448-433

Product Weight 9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health 1 Flammability 1 Reactivity 0

Last Revision
3/5/2010

BUSAN 1215

BUSAN is a registered trademark.

Buckman

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MILLS: BUSAN 1215 is used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

INDUSTRIAL WATER SYSTEMS: BUSAN 1215 is used for the control of algal, bacterial and fungal deposits in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

When this product is used to treat sewage and wastewater systems, seawater, and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, and the system water is not sent to a POTW; residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment.

When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes; effluent detection of chloramine should be conducted at least once per shift. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water process through a closed metered chemical feed system. The system operator must be trained by a Buckman representative in the use of the chemical feed system. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

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31

Buckman
USA

Buckman L. ories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108-1241 USA

(901) 278-0330 Tel
(901) 276-5343 Fax
buckman.com

March 16, 2010

Ms. Velma Noble, PM 31
Regulatory Management Branch I
Antimicrobial Division (7510)
U.S. Environmental Protection Agency
Room S-8855, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: Label Revisions: PR Notice 2007-4 Pesticide Container and Containment Rule
EPA Registration Numbers: 1448-432 and 1448-433

Dear Ms. Noble:

Buckman Laboratories submits the following amendment for the product labels listed below:

BCMW (EPA Reg. # 1448-432) BUSAN 1215 (EPA Reg. # 1448-433)

Please find enclosed the EPA application form 8570-1 and 5 copies of each draft revised label incorporating changes per comments from PR Notice 2007-4 regarding the Pesticide Container and Containment Rule.

If you have any questions or require any additional information pertaining to this action, please contact Crystal Brown at (901) 272-8258 (cwbrown@buckman.com) or myself at (901) 272-6228 (cfwatson@buckman.com).

Sincerely,

BUCKMAN USA

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

Please read instructions on reverse before comp[illegible] form. Form Approvec B No. 2070-0060, Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448-433	Velma Noble	☐ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
BUSAN 1215	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Amendment: Non-PRIA action.
ACTION: Revise the Storage & Disposal Section in order to comply with PR Notice 2007-4

Contact: cfwatson@buckman.com; FAX: (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watson	Sr. Regulatory Toxicologist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Carl F Watson	Sr. Regulatory Toxicologist	Carl F. Watson, Ph.D.	16 March 2010

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Crystal Brown
Buckman Laboratories,
1256 N. Mclean, Blvd.,
Memphis, TN 38108

APR - 1 2010

Subject: Bussan 1215
EPA Registration No.: 1448-433
Notification Date: March 1, 2010
EPA Receipt Date: March 3, 2010
Submission #: 429984

Dear Crystal Brown,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

Proposed notification request for alternative Trade name:

- Oxamine 6150.

General Comments

Based on a review of the submitted materials, your notification for a request for an alternative trade name is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Velma Noble
Product Manager -31
Regulatory Management Branch
Antimicrobials Division (7510P)

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

31

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
BUCKMAN LABORATORIES, INC./1448-433

2. EPA Product Manager
Velma Noble

3. Proposed Classification
- [x] None
- [ ] Restricted

4. Company/Product (Name)
BUCKMAN LABORATORIES, INC/BUSAN 1215

PM#
31

5. Name and Address of Applicant *(Include ZIP Code)*
BUCKMAN LABORATORIES, INC.
1256 North McLean, Boulevard
Memphis, TN 38108
- [ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Trade Name: OXAMINE 6150

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information
- [ ] Label
- [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions
- [ ] On Label
- [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
- [ ] Lithograph
- [ ] Paper glued
- [ ] Stenciled
- [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Crystal W. Brown, MS	Regulatory Specialist	901.272.8258

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
	Regulatory Specialist	(Stamped)
4. Typed Name: Crystal W. Brown, MS	5. Date: Mar 1, 2010	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

'ED STATES ENVIRONMENTAL PROTE[redacted]ION AGENCY

JUL 15 2008

Mr. Carl Watson, Ph.D.
Sr. Regulatory Toxicologist
Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Subject: **Busan 1215**
EPA Registration Number 1448-433
Application Dated June 6, 2007
Received Date June 11, 2007

Dear Mr. Watson:

The following label revisions submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Labeling:

O New Use: Industrial water systems

General Comment:

Should you have any questions concerning this letter please contact Drusilla Copeland at (703) 308-6224 or Velma Noble (70) 308-6233

Sincerely,

Velma Nobel
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped Label

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

BUSAN 1215

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products and in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

ACTIVE INGREDIENT(S)	
Ammonia (total)	7.59%
INERT INGREDIENTS	92. 41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

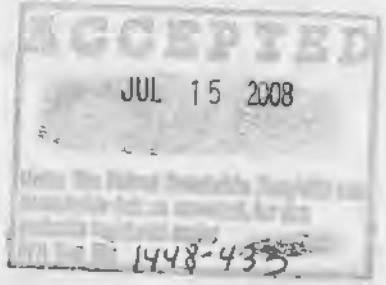
FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-278-0330 or 1-800-BUCKMAN for emergency medical treatment information.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wear protective eye-wear (goggles, face shield or safety glasses), impervious chemical-resistant gloves, and full body clothing (long sleeved shirt and long pants), socks and shoes when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MILLS: BUSAN 1215 is used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

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If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

INDUSTRIAL WATER SYSTEMS: BUSAN 1215 is used for the control of algal, bacterial and fungal deposits in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

When this product is used to treat sewage and wastewater systems, seawater, and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, and the system water is not sent to a POTW; residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment.

When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes; effluent detection of chloramine should be conducted at least once per shift. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

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Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources. .

CONTAINER DISPOSAL

PLASTIC: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

METAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Manufactured by

Buckman Laboratories, Inc.

1256 North McLean Blvd.
Memphis, Tennessee 38108, USA

(901) 278-0330 or 1-800-BUCKMAN

EPA Est. No.	1448-TN-1
EPA Reg. No.	1448-433
Product Weight	9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health **1** Flammability **1** Reactivity **0**

Last Revision 7/17/2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

July 9, 2008

MEMORANDUM

SUBJECT: Risk Assessment and Science Support Branch's (RASSB's) Review of Registrant's Response as Follow-up To 6/12/08 Teleconference with Agency Staff [ID No. 1448-433; Ammonia (Total) – 7.59 % (005302)]

FROM: Norm Cook, Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Velma Noble, Product Manager-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

DP BARCODE: None

Pesticide Chemical No: 005302

Background

Previous Registrant Submission

Previously, the registrant, Buckman Laboratories International, Inc., submitted an amendment for the product Busan 1215 to add a new use in industrial water systems. Busan 1215 is an [redacted], which is applied in conjunction with sodium hypochlorite (at a minimum of 1:1 molar ratio) to form monochloramine according to the amended label. The registrant proposes to use Busan 1215 in controlling algae, bacteria and fungi in "industrial cooling towers, recirculation cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing

Inert ingredient information may be entitled to confidential treatment

decorative fountains and ponds used for cooling purposes, sewage and wastewater systems." Busan 1215 is also intended to be used in both seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks.

Busan 1215 can be used in intermittent or continuous treatment, by mixing 0.5 fluid ounces of Busan 1215 with 1.0 fluid ounces of sodium hypochlorite (up to 15% wt/ml) to achieve a total chlorine residual of at lease 1 ppm in excess of the system oxidant demand. A total chlorine residual of 1 to 2 ppm for intermittent treatment and 0.5 to 1 ppm for continuous treatment is needed; the maximum total chlorine residual is 5 ppm in water for both intermittent and continuous treatment. The frequency and duration of the treatment vary depending upon the severity of the situation. Generally the water is treated for 5 to 60 minutes every 1 to 6 hours. An initial cleanup before treatment should be carried out for badly fouled systems.

RASSB Review of Previous Registrant Submission

For the proposed industrial water systems RASSB completed two sets of prior non-food assessments for: occupational exposures; hazard/dose response (toxicology); environmental: fate, modeling, hazards, and risks [Concentrations of Concern (COCs) exceedances]. These two sets of reviews were completed in March and May of 2008, including: a 3/10/08 RASSB memo which provided summary comments on the branch's position on various environmental reviews; and a 5/12/08 RASSB response to the registrant's previous proposals concerning data requirements and labeling.[1]

Present Registrant Response

Registrant Proposals and Information

As follow-up to the teleconference between the registrant and Agency representatives concerning RASSB's 5/12/08 review, the registrant has provided the following information via a 6/16/08 *email from Dennis L. Barbee (Buckman) to Velma Noble (USEPA)(containing proposed modified labeling and information on automated chloramine detection equipment)*:[2]

Registrant:

- Provided the following information to the Agency: proposed label language (2 p.); discussion of "Automated Chemical Feed Systems" (3 p.); Tech Manual Excerpt, "FILMTEC™ MEMBRANES, Water Chemistry and Pretreatment Biological Fouling Prevention" (4 p.); DATA SHEET, "CL17 Chlorine Analyzer" (4 p.); DATA SHEET, "APA 6000™ Ammonia/Monochloramine Analyzer" (4 p.).

- States that automated chloramine detection equipment (e.g., APA 6000™ Ammonia/Monochloramine Analyzer) can be used on the three industrial water systems

1 Note that the environmental modeling assessments for the three industrial water systems of concern to the Agency were completed in January, 2008.

2 This automated chloramine detection equipment will be used to detect residual levels of chloramine in effluents so that sodium metabisulfite can be added to neutralize chloramine residues.

of concern to RASSB. These three systems are: ***seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks (because typically control of mollusks occurs in once-through industrial water systems); and sewage and wastewater systems.***

- States that, when necessary, they will provide assistance and training to users of Busan 1215 and automated chloramine detection equipment.

- Recommends the following labeling language to address potential chloramine residues in effluents:

  When this product is used to treat sewage and wastewater systems, seawater and freshwater influent systems, and seawater desalination and reverse osmosis systems, residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment. If residual levels of chloramine are detected in the effluent, they can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected. Seawater desalination and reverse osmosis systems for which the pretreatment process includes dechlorination will neutralize the chloramine before it reaches the effluent and hence do not require the additional effluent monitoring and control equipment. ***Note:*** *If you do not understand the operation of the monitoring and neutralization equipment, please contact the equipment supplier for training and assistance.*

RASSB Review of Current Registrant Proposals and Information

RASSB has reviewed the above proposals and commends the registrant on their efforts to address Agency comments and concerns. However, considering our environmental concerns for the three industrial water systems which we believe provide potentially for "extensive outdoor exposure", we provide the following:

- As we have stated repeatedly, RASSB has concerns with three industrial water systems. These three systems are: ***seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks (because typically control of mollusks occurs in once-through industrial water systems); and sewage and wastewater systems.*** Considering this, we believe the use of the phrase "influent systems" is too general and does not address influent systems which are part of once-through industrial water systems - the systems we are primarily concerned with. We conclude that the first sentence of the proposed labeling be modified to read: "**When this product is used to treat sewage and wastewater systems, seawater and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment.**"

- Additionally, for the other Busan 1215 use patterns [**recirculating cooling water systems, evaporative condensers, influent water systems (which are not part of once-through systems), brewery and food pasteurizers, airwashers, paint spray booth**

sumps, and non-fish containing decorative fountains and ponds used for cooling purposes], we recommend the following labeling statements be added to the label for these scenarios:

> When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes, effluent detection of chloramine should be conducted at least once every eight hours of operation. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

In closing, the above represents RASSB's conclusions concerning the registrant's 6/16/08 proposals and information. If you have any questions, please contact RASSB.

cc: J. Breithaupt
N. Elkassabany
S. Gowda
S. Mostaghimi
R. Petrie
RASSB files

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

May 12, 2008

MEMORANDUM

SUBJECT: Risk Assessment and Science Support Branch's (RASSB's) Review of Registrant's 3/25/08 Response to RASSB's 3/10/08 Review of Proposed New Use of Busan 1215 in Industrial Water Systems [ID No. 1448-433; Ammonia (Total) – 7.59 % (005302)]

FROM: Norm Cook, Chief Norm Cook 5/12/08
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Velma Noble, Product Manager-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

DP BARCODE: D351621

Pesticide Chemical No: 005302

Background

Previous Registrant Submission

Previously, the registrant, Buckman Laboratories International, Inc., submitted an amendment for the product Busan 1215 to add a new use in industrial water systems. Busan 1215 is an [redacted], which is applied in conjunction with sodium hypochlorite (at a minimum of 1:1 molar ratio) to form monochloramine according to the amended label. The registrant proposes to use Busan 1215 in controlling algae, bacteria and fungi in "industrial cooling towers, recirculation cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers,

Inert ingredient information may be entitled to confidential treatment

airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems." Busan 1215 is also intended to be used in both seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks.

Busan 1215 can be used in intermittent or continuous treatment, by mixing 0.5 fluid ounces of Busan 1215 with 1.0 fluid ounces of sodium hypochlorite (up to 15% wt/ml) to achieve a total chlorine residual of at lease 1 ppm in excess of the system oxidant demand. A total chlorine residual of 1 to 2 ppm for intermittent treatment and 0.5 to 1 ppm for continuous treatment is needed; the maximum total chlorine residual is 5 ppm in water for both intermittent and continuous treatment. The frequency and duration of the treatment vary depending upon the severity of the situation. Generally the water is treated for 5 to 60 minutes every 1 to 6 hours. An initial cleanup before treatment should be carried out for badly fouled systems.

RASSB Review of Previous Registrant Submission

For the proposed industrial water systems RASSB completed non-food assessments for: occupational exposures; hazard/dose response (toxicology); environmental: fate, modeling, hazards, and risks [Concentrations of Concern (COCs) exceedances]. These reviews were submitted to the regulatory branch under separate cover memos, and for the environmental assessments RASSB provided summary comments in order to clarify the branch's position on the various environmental reviews. These comments, dated 3/10/08, were:

- "In these evaluations RASSB considers many of the proposed non-food industrial water systems as providing "limited outdoor exposure" (e.g., evaporative condensers, brewery and food pasteurizers). However, for three of the proposed non-food industrial water systems we consider them to be systems which provide for potentially "extensive outdoor exposure". These three systems are: ***seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks (because typically control of mollusks occurs in once-through industrial water systems); and sewage and wastewater systems***.

- Considering the point above, RASSB has completed environmental assessments which address both the "limited" and "extensive" outdoor exposure non-food industrial water systems. For the three "extensive outdoor exposure" systems:

  - We have assumed that the majority of residues likely to be found in effluents, and eventually surface waters, would be chloramines.

  - Our modeling estimates (see three sister reviews for environmental modeling) indicate that chloramine COCs for aquatic species are exceeded for all three of these industrial water systems.

  - These chloramine modeling estimates indicate that these proposed industrial water system uses provide for unacceptable risks to aquatic species.

- Considering point 2 above, we also note that a previous Busan 1215 label submitted to the Agency stated: "*If the effluent from a Busan 1215 application is discharged into a surface water source, automated chloramine detection and neutralization equipment will be required.*" The revised label under consideration no longer contains this statement. Additionally, we are not sure if such automated systems are/can be used in large industrial water systems such as once-through cooling water systems.

- Relative to the above points, we conclude that to support proposed registration of the three non-food industrial water systems that provide for "extensive outdoor exposure", the registrant must either: (a) submit additional extensive environmental fate, monitoring, and ecological effects data to the Agency to address the amount, extent, and duration of (presumably chloramine) residues which are being discharged in effluents and into receiving surface waters; or (b) amend the label to indicate that this product can *only be used* in these three industrial water systems when automated chloramine detection and neutralization equipment is present for detecting and neutralizing chloramines in effluents from these systems (*i.e., seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks; and sewage and wastewater systems*). (As discussed above, we are not certain if such automated equipment is available for large industrial water systems.) If, because of the way these three industrial water systems operate, automated chloramine detection and neutralization equipment cannot be utilized, then the data discussed in (a), and shown in the attached appendix, are required."

Present Registrant Submission (3/25/08)

Registrant Proposals

In the present submission [*3/25/08 email from Dennis L. Barbee (Buckman) to Velma Noble (USEPA) along with modified label*], the registrant:

- Believes that monochloramine (MCA) will degrade in industrial water systems and not be found in effluent. However, the registrant has provided no data to support this claim;

- Is not aware of a feasible automated process that would detect MCA in effluents; and

- Recommends the following labeling language to address potential MCA residues in effluents:

  When this product is used to treat sewage and wastewater systems, seawater, and freshwater influent systems, or seawater desalination and reverse osmosis systems, effluent detection of chloramine should be conducted at least once every eight hours of operation. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

RASSB Review of 3/25/08 Registrant Proposals

RASSB staff met on 5/6/08 to review and evaluate the registrant's proposals. Based upon this review we offer the following comments:

- The registrant has provided no data to support their claim that monochloramine (MCA) will degrade in industrial water systems and not be found in effluent.

- The registrant's proposed labeling language is not likely to protect nontarget aquatic organisms in receiving waters. To state that chloramine detection *should* be conducted at least once every eight hours of operation provides for the likelihood that: (a) such detection may not occur at a facility; and (b) consequently, chloramine Concentrations of Concern (COCs) for aquatic species may be exceeded (resulting in unacceptable risks to such species) during use of Busan 1215.

- Considering the above points, RASSB concludes that:

  - Use of Busan 1215 in **recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes** *should* provide for minimal exposures and risks to nontarget aquatic organisms. However, to ensure that this occurs we recommend the following labeling statements appear on the label for these scenarios:

    When this product is used to treat *recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes*, effluent detection of chloramine should be conducted at least once every eight hours of operation. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

  - The registrant's 3/25/08 proposals concerning use of Busan 1215 in seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks; and sewage and wastewater systems do not provide for adequate mitigation of potential risks to aquatic organisms. Considering this, we conclude, once again, that to support proposed registration of these three industrial water systems, the registrant must submit additional extensive environmental fate, monitoring, and ecological effects data to the Agency to address the amount, extent, and duration of chloramine residues which are being discharged in effluents and into receiving surface waters. These data requirements are outlined in the attached appendix.

Conference Call
5/14/08 - 10:00 Am
"Set up meeting with Norm Brant"
end of May 27.28.29
Dennis Barbe
Call Walter
Conf # 8621
45-60 Days
July 15, 08
2nd Time Registration

Appendix

Environmental [Ecological, Fate, Field (Monitoring)] Data Requirements for Industrial Water Systems Providing For "Extensive Outdoor Exposure"[1]

(5/12/08)

Introduction

Initially, the registrant is required to identify: (a) the types of industrial water systems that the product is intended to be used in; and (b) those residues likely to be discharged into effluents and surface waters: e.g., parent compound (active ingredient) and/or major metabolites or degradates. Determination of residues likely to be found in effluents and surface waters enables the Agency to determine what compound(s) are to be tested in the following environmental studies.

Note that the Agency uses these environmental [including field (typically monitoring)] data, along with environmental modeling to perform screening level environmental risk assessments: i.e., develop preliminary Risk Quotients (RQs) and determine if environmental Levels of Concern (LOCs) are exceeded. Additionally, the Agency may determine that human exposure and risk assessments are also required. At this time, however, the need for human health assessments will be determined on a case-by-case basis.

Required Environmental Effects and Fate Data

1. To support registration of once-through industrial water systems, the following ecological effects and environmental data are required:

a. **Required Ecological Effects Data**:

Guideline Number	Description of Data Requirement
850.1010:	Aquatic invertebrate acute EC_{50} using *Daphnia magna* (using TGAI and TEP);
850.1075:	Fish acute LC_{50}s with a coldwater (rainbow trout, preferred) and a warmwater (bluegill sunfish, preferred) species (using TGAI and Typical End-Use Product (TEP);
850.1300/ 850.1400:	Fish early-life stage and aquatic invertebrate life-cycle studies (using TGAI and most sensitive species - freshwater or estuarine/marine);
850.2100:	Avian acute oral LD_{50} with bobwhite quail (preferred) or mallard duck (using Technical Grade Active Ingredient (TGAI);

[1] These industrial water systems typically include: once-through cooling water systems; seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks; and sewage and wastewater systems.

850.4225: Seedling emergence - dose response using rice (*Oryza sativa*); and
850.4400/
850.5400: Aquatic plant growth (algal and aquatic plant toxicity) - Tier II (using TGAI or TEP).

b. **Conditionally-Required (CR) Ecological Effects Data**:

850.1025/
850.1035/
850.1045/
850.1055/
850.1075: Acute LC_{50}s/EC_{50}s using estuarine/marine organisms (fish, mollusk, shrimp) species (using TGAI and TEP);
850.1500: Fish (freshwater and/or estuarine/marine species) life cycle study (using TGAI);
850.1710/
850.1730/
850.1850: Aquatic organism bioavailability/biomagnification/toxicity tests (using TGAI or PAIRA);
850.1735: Whole sediment, acute invertebrates (freshwater) (using TGAI);
850.1740: Whole sediment, acute invertebrates (estuarine/marine) (using TGAI);
850.1950: Field testing for aquatic organisms (estuarine/marine) (using TEP);
850.2200: Avian dietary LC_{50} with bobwhite quail and/or mallard duck (using TGAI);
850.2300: Avian reproductive studies with bobwhite quail and/or mallard duck (using TGAI); and
None: Whole sediment - chronic invertebrates (freshwater and/or estuarine/marine) (using TGAI or TEP).

c. **Required Environmental Fate Data**:

Guideline Number	Description of Data Requirement
161-1/835.2120:	Hydrolysis study (using Technical Grade Active Ingredient (TGAI) or Pure Active Ingredient, Radio-labeled) (PAIRA)).[2]
835.2240:	Photodegradation in water (using TGAI or PAIRA);
835.1230:	Adsorption/desorption studies (using TGAI or PAIRA);
835.4300:	Aerobic aquatic metabolism (using TGAI or PAIRA);
835.4400:	Anaerobic aquatic metabolism (using TGAI or PAIRA);

d. **Conditionally-Required (CR) Environmental Fate Data**:

850.1730: Accumulation studies in fish (fish BCF);
850.1950: Accumulation studies in aquatic nontarget organisms;
835.4100: Aerobic soil metabolism (using TGAI or PAIRA);

[2] OPP's study protocol, 161-1, is the preferred method to use.

840.1100: Aquatic field study (using Typical End-use Product (TEP)).

2. Additionally, for proposed new uses for these types of industrial water systems, RASSB is coordinating science review efforts with the Office of Water (OW) and with certain USEPA Regional Offices to determine:

a. What issues, if any, that OW and/or Regions may have with the proposed use pattern; and

b. What ecological effects and environmental fate data requirements, as outlined above, can be correlated with OW's data requirements or needs (in an effort to avoid duplication of data requirements).

3. As presented above, most testing is performed on TGAI, TEP, or PAIRA. However, in those instances where the Agency believes that the metabolites or degradates of the parent compound are more toxic, persistent, bioaccumulative, or have been shown to cause adverse effects in mammalian and/or aquatic reproductive studies, data on those metabolites and degradates are required to support registration.

"Dennis L. Barbee" <dlbarbee@buckman.com>
07/16/2008 09:56 AM

To Drusilla Copeland/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA
cc "Richard A. Clark" <raclark@buckman.com>
bcc
Subject FW: Review for 1448-433

Hi Dru - As discussed this AM we propose the following language for the label. "

"When this product is used to treat sewage and wastewater systems seawater and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, and the system water is not sent to a POTW, residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment. ~~However for system water~~ that is sent to a POTW, ~~chloramine monitoring~~ would not be required. "
Call me at 901.272.8248 and let me know what you guys think.

Dennis

7/16/08

Talked w/ Siroos M. about the changes to the RASSB label language described above. Siroos was ok with the language proposed above with the cross outs. This is the language we accepted.

Dennis Edwards
7/16/08

"Dennis L. Barbee"
<dlbarbee@buckman.com>
07/15/2008 02:58 PM

To Drusilla Copeland/DC/USEPA/US@EPA
cc Velma Noble/DC/USEPA/US@EPA, "Richard A. Clark" <raclark@buckman.com>, "'Thomas E. McNeel'" <temcneel@buckman.com>, <cfwatson@buckman.com>,
bcc
Subject RE: Review for 1448-433

Hi Dru - We have reviewed RASSBs response and would like to propose the following minor change for clarification. RASSB has recommended the following:

"When this product is used to treat sewage and wastewater systems, seawater and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment."

We would like to amend this statement to read:

"When this product is used to treat sewage and wastewater systems that discharges directly to the environment, seawater and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment."

RASSBs second proposed condition was as follows:

When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes, effluent detection of chloramine should be conducted at least once every eight hours of operation. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

For the second condition we would like to propose the change identified below:

We would like to amend this section to read as follows:
When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes, effluent detection of chloramine should be conducted at least once per shift. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

This change is requested due to the fact that many operation run various shift lengths.

Call me at 901.272.8248 and let me know what you guys think.

Dennis

-----Original Message-----
From: Copeland.Drusilla@epamail.epa.gov [mailto:Copeland.Drusilla@epamail.epa.gov]
Sent: Tuesday, July 15, 2008 11:21 AM
To: dlbarbee@buckman.com
Cc: Noble.Velma@epamail.epa.gov

Subject: Review for 1448-433

Here it is Dennis, Let me know what you want to do. Thanks
----- Forwarded by Drusilla Copeland/DC/USEPA/US on 07/15/2008 12:18 PM

Norm Cook/DC/USEPA/US
07/09/2008 04:34 PM

To: Margaret Gregory/DC/USEPA/US@EPA

cc: Dennis Edwards/DC/USEPA/US@EPA, Drusilla Copeland/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, elkassabany.nader@epa.gov, Siroos Mostaghimi/DC/USEPA/US@EPA, Rick Petrie/DC/USEPA/US@EPA, James Breithaupt/DC/USEPA/US@EPA, Norm Cook/DC/USEPA/US@EPA

Subject: Ammonia Review for logout

(See attached file: July-2008-RASSB response folowing 6-12-08 teleconference-mem.doc)

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 380282	**Registration#:** 1448-433	**Petition #:**
Fee Category: A500	**PRIA Decision Time Frame:** 9 months	
Submitted by Velma Noble/Drusilla Copeland	**Branch:** RMBI	**Date:** 5/14/08
Company: : Buckman Laboratories, Inc.		
Original Due Date: 3/28/08	**Proposed New Due Date:** 7/15/08	
Previous Negotiated Due Dates: 5/14/08		
Is the "Fix" in-house? No	**If not, date "Fix" expected:**	

Issue (describe in detail): Additional data are needed to support 3 of approximately 12 water treatment use patterns due to environmental risk concerns. The company renegotiated and proposed labeling which they believed would address the problem. However, we believe the labeling will not address the concerns for three specific uses and that additional data are needed.

Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D)
Product Chemistry: ___ **Acute Tox:** ___ **Efficacy:** ____ **Labeling:** ____ **Other (describe):** __X__
Environmental fate and eco data are needed.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

The company was faxed a copy of the most recent science review on 5/13 and a conference call was held on 5/14 to discuss options. As a result, the company has requested a PRIA time extension to allow a conference call with our scientists to take place to discuss what is needed to support one of the three uses which have environmental risk concerns. The company wants this one use, reverse-osmosis. The conference call will be scheduled within the next 2 to 2 ½ weeks.

"75 Day" Letter sent? Yes _____ **Date** **_X___No and reason for none?**
A letter will be sent in the next 5 to 7 days.

Rationale for Proposed Due Date:

The proposed date allows the AD sufficient time to schedule a conference call and then review supporting materials that the company may submit..

Registrant notified that this is the last negotiation? **_X__Yes __Not Applicable**

Approve:	**Disapprove:**

If disapproved, action to be taken:

OD or DOD Signature:	**Date:** 5-14-08

Drusilla Copeland/DC/USEPA/US
05/14/2008 11:49 AM

To Dennis Edwards/DC/USEPA/US@EPA
cc
bcc
Subject Extension Fw: Reg# 1448-433

----- Forwarded by Drusilla Copeland/DC/USEPA/US on 05/14/2008 11:48 AM -----

"Dennis L. Barbee" <dlbarbee@buckman.com>
05/14/2008 10:58 AM

To Drusilla Copeland/DC/USEPA/US@EPA
cc
Subject FW: Reg# 1448-433

Hi Ms Copeland - I would like to thank you for facilitating our conference call regarding Buckman's amendment request regarding the Buckman product Busan 1215 (EPA Reg No 1448-433) this morning. To facilitate the amendment process for this action, Buckman requests that the Agency grant an extension on this action until 15 July 08, which will allow Buckman sufficient time to present information and RASSB to review the information to address the Agency's concerns in the RASSBs review dated 12 May 08. Please advise on your acceptance of this request.

Thanks

Dennis L. Barbee
Buckman Laboratories International, Inc.

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 380292	**Registration#: 1448-433**	**Petition #:**

Fee Category: A50	**PRIA Decision Time Frame:** 9 months	
Submitted by Velma Noble/Drusilla Copeland	**Branch:** RMBI	**Date: 3/27/08**
Company: : Buckman Laboratories, Inc.		
Original Due Date: 3/28/08	**Proposed New Due Date:** 3/14/08	
Previous Negotiated Due Dates: None		
Is the "Fix" in-house? Yes	**If not, date "Fix" expected:**	

Issue (describe in detail): Three uses have potential for significant environmental exposure. Label language was proposed to mitigate the environmental exposure. The registrant countered with revised language which needs science review.

Summary of Deficiency Type(s): **Not Submitted (N)** **Deficiencies (D)**
Product Chemistry: ___ **Acute Tox:** ___ **Efficacy:** ___ **Labeling:** __X_ **Other (describe):** ___

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

The company was called and emailed a letter on 3/25/08 which contained the revised language. The company emailed a rebuttal with a revised label and time extension on 3/26/08.

"75 Day" Letter sent? No **Date** ___ **No and reason for none?**

Rationale for Proposed Due Date:

The proposed date allows AD sufficient time to complete our review of the revised label.

Registrant notified that this is the last negotiation? ___ **Yes** _X**Not Applicable 1st renegot.**

Approve:	**Disapprove:**

If disapproved, action to be taken:

OD or DOD Signature:	**Date:** 3-28-08

"Dennis L. Barbee" <dlbarbee@buckman.com>
03/27/2008 09:34 AM

To Drusilla Copeland/DC/USEPA/US@EPA
cc Velma Noble/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, "'Carl Watson'" <cfwatson@buckman.com>
bcc
Subject RE: Reg# 1448-433

Hi Dru/Velma - Thanks for the information. To facilitate the amendment process for this action, Buckman requests that a 45-day extension be granted on this action. Please advise on your acceptance of this request.

Thanks

Dennis L. Barbee

From: Copeland.Drusilla@epamail.epa.gov [mailto:Copeland.Drusilla@epamail.epa.gov]
Sent: Wednesday, March 26, 2008 2:42 PM
To: dlbarbee@buckman.com
Cc: Noble.Velma@epamail.epa.gov; Edwards.Dennis@epamail.epa.gov
Subject: Reg# 1448-433

Hi Dennis, Per our conference call on 3/25/08. Your company agreed to revise the label to meet the concerns expressed in the letter. Since automatic chloramine detection systems are not readily available you proposed alternative language. On the revised label under heading "Industrial Water System" it states that when this product is used to treat these water systems ".....effluent detection of chloramine should be conducted at least once every eight hours of operation". Our science branch told us they need more time to review your proposed language and discuss whether the language is acceptable or propose some changes . They indicate they should be able to discuss this relatively quickly. Based on our discussions we believe we should be able to get back to you by May 14. This is the time extension needed in order for us to react to your proposal.

Email me and Velma to let us know if you agree or disagree with the new terms. Thanks

=

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

March 10, 2008

MEMORANDUM

SUBJECT: Risk Assessment and Science Support Branch's (RASSB's) Summary Comments RE: Environmental (Hazards, Risks, Modeling, and Fate) Reviews of Proposed New Use of Busan 1215 in Industrial Water Systems [ID No. 1448-433; Ammonia (Total) – 7.59 % (005302)]

FROM: Norm Cook, Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Velma Noble, Product Manager-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

DP BARCODE: None

Pesticide Chemical No: 005302

Introduction

The registrant, Buckman Laboratories International, Inc., has submitted an amendment for the product Busan 1215 to add a new use in industrial water systems. Busan 1215 is an [redacted], which is applied in conjunction with sodium hypochlorite (at a minimum of 1:1 molar ratio) to form monochloramine according to the amended label. The registrant proposes to use Busan 1215 in controlling algae, bacteria and fungi in "industrial cooling towers, recirculation cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater

Inert ingredient information may be entitled to confidential treatment

desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems." Busan 1215 is also intended to be used in both seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks.

Busan 1215 can be used in intermittent or continuous treatment, by mixing 0.5 fluid ounces of Busan 1215 with 1.0 fluid ounces of sodium hypochlorite (up to 15% wt/ml) to achieve a total chlorine residual of at lease 1 ppm in excess of the system oxidant demand. A total chlorine residual of 1 to 2 ppm for intermittent treatment and 0.5 to 1 ppm for continuous treatment is needed; the maximum total chlorine residual is 5 ppm in water for both intermittent and continuous treatment. The frequency and duration of the treatment vary depending upon the severity of the situation. Generally the water is treated for 5 to 60 minutes every 1 to 6 hours. An initial cleanup before treatment should be carried out for badly fouled systems.

RASSB Summary Comments Concerning Environmental (Ecological Hazards, Environmental Risks, and Environmental Fate) Reviews

For the proposed industrial water systems RASSB has completed non-food assessments for: occupational exposures; hazard/dose response (toxicology); environmental: fate, modeling, hazards, and risks [Concentrations of Concern (COCs) exceedances]. These reviews have been submitted to the regulatory branch under separate cover memos.

For the environmental assessments we wanted to provide some summary comments in order to clarify the branch's position on these reviews:

- In these evaluations RASSB considers many of the proposed non-food industrial water systems as providing "limited outdoor exposure" (e.g., evaporative condensers, brewery and food pasteurizers). However, for three of the proposed non-food industrial water systems we consider them to be systems which provide for potentially "extensive outdoor exposure". These three systems are: ***seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks (because typically control of mollusks occurs in once-through industrial water systems); and sewage and wastewater systems.***

- Considering the point above, RASSB has completed environmental assessments which address both the "limited" and "extensive" outdoor exposure non-food industrial water systems. For the three "extensive outdoor exposure" systems:

  - We have assumed that the majority of residues likely to be found in effluents, and eventually surface waters, would be chloramines.

  - Our modeling estimates (see three sister reviews for environmental modeling) indicate that chloramine COCs for aquatic species are exceeded for all three of these industrial water systems.

  - These chloramine modeling estimates indicate that these proposed industrial water

system uses provide for unacceptable risks to aquatic species.

- Considering point 2 above, we also note that a previous Busan 1215 label submitted to the Agency stated: "*If the effluent from a Busan 1215 application is discharged into a surface water source, automated chloramine detection and neutralization equipment will be required.*" The revised label under consideration no longer contains this statement. Additionally, we are not sure if such automated systems are/can be used in large industrial water systems such as once-through cooling water systems.

- Relative to the above points, we conclude that to support proposed registration of the three non-food industrial water systems that provide for "extensive outdoor exposure", the registrant must either: (a) submit additional extensive environmental fate, monitoring, and ecological effects data to the Agency to address the amount, extent, and duration of (presumably chloramine) residues which are being discharged in effluents and into receiving surface waters; or (b) amend the label to indicate that this product can *only be used* in these three industrial water systems when automated chloramine detection and neutralization equipment is present for detecting and neutralizing chloramines in effluents from these systems (*i.e., seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks; and sewage and wastewater systems*). (As discussed above, we are not certain if such automated equipment is available for large industrial water systems.) If, because of the way these three industrial water systems operate, automated chloramine detection and neutralization equipment cannot be utilized, then the data discussed in (a), and shown in the attached appendix, are required.

In closing, the above represents RASSB's summary comments concerning our environmental assessments. If you have any questions, please contact RASSB.

cc: N. Elkassabany
S. Gowda
S. Mostaghimi
R. Petrie
J. Tao
RASSB files

Appendix

Environmental [Ecological, Fate, Field (Monitoring)] Data Requirements for Industrial Water Systems Providing For "Extensive Outdoor Exposure"[1]

(3/10/08)

Introduction

Initially, the registrant is required to identify: (a) the types of industrial water systems that the product is intended to be used in; and (b) those residues likely to be discharged into effluents and surface waters: e.g., parent compound (active ingredient) and/or major metabolites or degradates. Determination of residues likely to be found in effluents and surface waters enables the Agency to determine what compound(s) are to be tested in the following environmental studies.

Note that the Agency uses these environmental [including field (typically monitoring)] data, along with environmental modeling to perform screening level environmental risk assessments: i.e., develop preliminary Risk Quotients (RQs) and determine if environmental Levels of Concern (LOCs) are exceeded. Additionally, the Agency may determine that human exposure and risk assessments are also required. At this time, however, the need for human health assessments will be determined on a case-by-case basis.

Required Environmental Effects and Fate Data

1. To support registration of once-through industrial water systems, the following ecological effects and environmental data are required:

a. **Required Ecological Effects Data**:

Guideline Number	Description of Data Requirement
850.1010:	Aquatic invertebrate acute EC_{50} using *Daphnia magna* (using TGAI and TEP);
850.1075:	Fish acute LC_{50}s with a coldwater (rainbow trout, preferred) and a warmwater (bluegill sunfish, preferred) species (using TGAI and Typical End-Use Product (TEP);
850.1300/ 850.1400:	Fish early-life stage and aquatic invertebrate life-cycle studies (using TGAI and most sensitive species - freshwater or estuarine/marine);
850.2100:	Avian acute oral LD_{50} with bobwhite quail (preferred) or mallard duck (using Technical Grade Active Ingredient (TGAI);

[1] These industrial water systems typically include: once-through cooling water systems; seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks; and sewage and wastewater systems.

850.4225: Seedling emergence - dose response using rice (*Oryza sativa*); and
850.4400/
850.5400: Aquatic plant growth (algal and aquatic plant toxicity) - Tier II (using TGAI or TEP).

b. **Conditionally-Required (CR) Ecological Effects Data**:

850.1025/
850.1035/
850.1045/
850.1055/
850.1075: Acute LC_{50}s/EC_{50}s using estuarine/marine organisms (fish, mollusk, shrimp) species (using TGAI and TEP);
850.1500: Fish (freshwater and/or estuarine/marine species) life cycle study (using TGAI);
850.1710/
850.1730/
850.1850: Aquatic organism bioavailability/biomagnification/toxicity tests (using TGAI or PAIRA);
850.1735: Whole sediment, acute invertebrates (freshwater) (using TGAI);
850.1740: Whole sediment, acute invertebrates (estuarine/marine) (using TGAI);
850.1950: Field testing for aquatic organisms (estuarine/marine) (using TEP);
850.2200: Avian dietary LC_{50} with bobwhite quail and/or mallard duck (using TGAI);
850.2300: Avian reproductive studies with bobwhite quail and/or mallard duck (using TGAI); and
None: Whole sediment - chronic invertebrates (freshwater and/or estuarine/marine) (using TGAI or TEP).

c. **Required Environmental Fate Data**:

Guideline Number	Description of Data Requirement
161-1/835.2120:	Hydrolysis study (using Technical Grade Active Ingredient (TGAI) or Pure Active Ingredient, Radio-labeled) (PAIRA)).[2]
835.2240:	Photodegradation in water (using TGAI or PAIRA);
835.1230:	Adsorption/desorption studies (using TGAI or PAIRA);
835.4300:	Aerobic aquatic metabolism (using TGAI or PAIRA);
835.4400:	Anaerobic aquatic metabolism (using TGAI or PAIRA);

d. **Conditionally-Required (CR) Environmental Fate Data**:

850.1730: Accumulation studies in fish (fish BCF);
850.1950: Accumulation studies in aquatic nontarget organisms;
835.4100: Aerobic soil metabolism (using TGAI or PAIRA);

[2] OPP's study protocol, 161-1, is the preferred method to use.

840.1100: Aquatic field study (using Typical End-use Product (TEP)).

2. Additionally, for proposed new uses for these types of industrial water systems, RASSB is coordinating science review efforts with the Office of Water (OW) and with certain USEPA Regional Offices to determine:

a. What issues, if any, that OW and/or Regions may have with the proposed use pattern; and

b. What ecological effects and environmental fate data requirements, as outlined above, can be correlated with OW's data requirements or needs (in an effort to avoid duplication of data requirements).

3. As presented above, most testing is performed on TGAI, TEP, or PAIRA. However, in those instances where the Agency believes that the metabolites or degradates of the parent compound are more toxic, persistent, bioaccumulative, or have been shown to cause adverse effects in mammalian and/or aquatic reproductive studies, data on those metabolites and degradates are required to support registration.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 10, 2008

MEMORANDUM

SUBJECT: Environmental Fate Assessment of Aqueous Ammonia (7.59% Total) for the Proposed Use in Industrial Water Systems

PC Code: 005302 **DP Barcode:** D342580
CAS No. : 7664-41-7
Chemical: Aqueous Ammonia (Total)

FROM: Srinivas Gowda, Microbiologist/Chemist Srinivas Gowda
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

TO: Velma Noble, Team Leader, PM 31
Regulatory Management Branch I
Antimicrobials Division (7510P)

THRU: Siroos Mostaghimi, Team Leader, Team one Siroos Mostaghimi
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

Norman Cook, Branch Chief Norman A Cook
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

Attached is the Environmental Fate Assessment on Aqueous Ammonia (Total) to support the proposed registration of Busan 1215 in industrial water systems.

AQUEOUS AMMONIA (Total)

NEW USE REGISTRATION
(Industrial Water Systems Use)

ENVIRONMENTAL FATE ASSESSMENT

EXECUTIVE SUMMARY

Ammonia occurs naturally in the environment as a result of the decay of organic matter. Ammonia is used as a fertilizer that is applied by injection into fields of growing crops, and to control microbial growth in stored fruits, hay, and grains. Ammonia is also produced synthetically. Busan 1215 is a microbiocide proposed for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paper products and in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems. Busan 1215 (7.59% total ammonia) is a colorless alkaline liquid with a pungent odor that is used in conjunction with sodium hypochlorite at a 3:2 molar ratio to create a family of microbicidal compounds called chloramines. Chloramines are a slower-acting, less aggressive, oxidizing microbiocide. In aqueous solution, ammonia exists in equilibrium with ammonium hydroxide. The chemical structure of aqueous ammonia (Figure 1) is as follows:

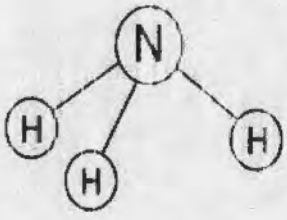

Figure 1. Structure of Ammonia (NH_3)

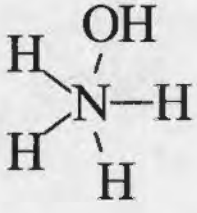

Figure 2. Ammonium hydroxide (NH_4OH)

Chloramines are formed when ammonia (NH_3) from the Busan 1215 reacts with chlorine from the sodium hypochlorite to produce a mixture of monochloramine (NH_2Cl), dichloramine ($NHCl_2$), or nitrogen trichloride (NCl_3). Monochloramine (NH_2Cl) is the preferred form of chloramine for microbiocidal purposes. The submitter stated that if Busan 1215 is used correctly, the primary chloramine species would be monochloramine. For the purpose of this review, monochloramines will be referred to as chloramine and only data on monochloramine will be discussed. The chemical structure of chloramine (Figure 3) is as follows:

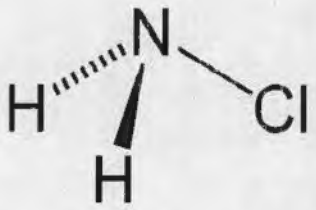

Figure 3. Structure of Chloramine (NH_2Cl)

Ammonia

None of the required guideline studies for an environmental fate assessment of ammonia have been submitted.

The Agency has used its databases (EPI Suite) and published literature (TOXNET) for the environmental fate assessment of aqueous ammonia (total). This information indicates the following:

> Ammonia is adsorbed on soil, sediment particles, and colloids in water which can result in high concentrations of sorbed ammonia in oxidized sediments. However, under normal aerobic conditions in water, ammonia is rapidly biodegraded by bacteria to nitrate through a process known as nitrification. The rate of degradation can be affected by temperature, oxygen supply, and pH of the water. Under anaerobic conditions, the adsorptive capacity is decreased and ammonia is released to the water column or to an oxidized sediment layer. In clay soils, the ammonia ion tends to be adsorbed on the negative adsorption sites of clay colloids and may substitute for potassium in the lattice structure of a clay mineral. Under abiotic conditions, ammonia is oxidized by ozone, catalyzed by the hydroxide ion over the pH 7-9 range. In the atmosphere, ammonia combines with sulfate ions in the atmosphere (acid pollutants), or in washout by rainfall, resulting in a rapid return to the soil with an estimated atmospheric half-life of a few days. Global estimated concentrations of ammonia in the air are approximately 0.6-3 ppb. Ammonia does not bioaccumulate in aquatic organisms.

Chloramines

None of the required guideline studies for an environmental fate assessment of chloramine have been submitted.

The Agency has used its databases (EPI Suite) and open literature (TOXNET) for the environmental fate assessment of chloramine. This information indicates the following:

> Chloramine hydrolyzes slowly in aqueous solution (Rice and Gomez-Taylor, 1986). Monochloramine's disappearance from water is primarily a function of pH and salinity: its half-life increases with increasing pH and decreases with increasing salinity. Monochloramine is expected to decompose via chlorine transfer to yield organic

nitrogen-containing compounds (Jolley and Carpenter, 1983). Vikesland and colleagues (2001) stated "Unfortunately, in spite of the long history of chloramine use in [water] treatment, the fate of chloramine in distribution systems and the characteristics and processes that influence their stability are largely unknown". Chloramine half-lives in natural water range from 9 to 420 hours (Yamamoto et al., 1988). Ultraviolet light depletes only free chlorine, whereas chloramines seem to be quite stable in sunlight.

Chloramines are highly water soluble, and it is unexpected that chloramines bioaccumulate in the aquatic or terrestrial food chains. Based on the dearth of published literature, biodegradation is not expected to be a major degradation pathway. Inorganic chloramine loss from the water column may occur via adsorption and reaction with suspended solids and bottom sediments (Milne, 1991). However, benthic demand has not been highly studied and is very site specific and therefore difficult to generalize. Studies describing the fate of chloramines in ambient air do not exist. EPI Suite predicts a long air half-life and volatilization from dry soil with a low air/octanol coefficient (1.377). Monochloramines are very water soluble and thus susceptible to removal from the atmosphere by rain. Environmental fate data of chloramines in soil have not been published. Relatively little data were found regarding inorganic chloramine concentrations in ambient air, groundwater, sediments, soils or biota. A 1984 survey of some U.S. utilities using chloramines as a primary disinfectant (Trussell and Kreft, 1984) showed a range of 1.5-2.5 mg/L in the distribution system.

Required Environmental Fate Data

For the proposed registration of the industrial water systems use, RASSB considers many of the proposed water systems as providing "limited outdoor exposure" (e.g., evaporative condensers, brewery and food pasteurizers). However, for three of the proposed non-food industrial water systems we consider them to be systems which provide for potentially "extensive outdoor exposure". These three systems are: ***seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks (because typically control of mollusks occurs in once-through industrial water systems); and sewage and wastewater systems.***

For these three industrial water systems extensive environmental fate data may be required. We have assumed that the majority of residues likely to be found in effluents, and eventually surface waters, from these systems would be chloramines. However, as outlined in a sister review containing summary environmental comments and an Appendix outlining environmental data required (copy attached), we conclude that:

The registrant must either: (a) submit additional extensive environmental fate, monitoring, and ecological effects data to the Agency to address the amount, extent, and duration of (presumably chloramine) residues which are being discharged in effluents and into receiving surface waters; or (b) amend the label to indicate that this product can *only be used* in these three industrial water systems when automated chloramine detection and neutralization equipment is present for detecting and neutralizing chloramines in effluents from these

systems (*i.e., seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks; and sewage and wastewater systems*). If, because of the way these three industrial water systems operate, automated chloramine detection and neutralization equipment cannot be utilized, then the data discussed in (a), and shown in the attached appendix, are required.

I. Environmental Fate Assessment - Ammonia

Abiotic - Ammonia

None of the required guideline studies for an environmental fate assessment of Ammonia have been submitted.

Biotic - Ammonia

None of the required guideline studies for an environmental fate assessment of Ammonia have been submitted.

EPI Suite Information - Ammonia

The Agency has used its databases (EPI Suite) to conduct the environmental fate risk assessment. EPI Suite estimates physical/chemical properties, environmental fate and transport, and includes estimation programs for Log K_{ow}, K_{oc}, Atmospheric Oxidation Potential, Henry's Law Constant, Water Solubility, Melting Point, Boiling Point, Vapor Pressure, Biodegradation, Bioconcentration Factor, Hydrolysis, Sewage Treatment Plant Removal, Fugacity Modeling, and Multimedia Modeling.

Ammonia is not bioaccumlative (log K_{ow} is -1.38) and poses low concern for bioconcentration in aquatic organisms due to a bioconcentration factor (BCF) of 3.162. Ammonia is highly soluble in water (4.82×10^5 mg/L) and mobile in soils based upon an estimated K_{oc} value of 14.3. Ammonia is expected to volatize from dry soil surfaces with an estimated vapor pressure of 7510 mm Hg.

The following fate properties were obtained from EPA internal environmental fate databases, open literature, and from the Estimation Programs Interface (EPI) Suite:

1. Vapor Pressure: 7510 mm Hg at 25°C.
2. Henry's Law Constant (air/water partition coefficient): 1.61×10^{-5} atm-m^3/mole at 25°C.
3. K_{oc} (organic carbon ratio in soil): 14.3, mobile.
4. Log K_{ow} (octanol/water partition coefficient): -1.38.
5. The hydrolysis rate constant could not be estimated for the chemical structure of ammonia.
6. Water solubility is 4.82×10^5 mg/L at 25°C.
7. The reaction of vapor-phase ammonia with photochemically-produced hydroxyl

radicals in the atmosphere could not be estimated due to its chemical structure.
8. The fugacity half-lives of ammonia in air, water, soil and sediment are 1 x 10^5 hours, 360 hours, 720 hours and 3240 hours, respectively (estimated).
9. Log BCF: 0.500; BCF: 3.162.
10. Specific gravity/density: 0.7710 g/L at 760 mm Hg.
11. pKa: 9.25 at 25°C.

The Henry's Law constant for ammonia indicates that it is expected to be volatile from water surfaces. The log K_{ow} (-1.38) indicates that bioaccumulation in aquatic organisms like fish is not likely and that the soil/sediment adsorption coefficient will be low. Ammonia is highly soluble in water (4.82 x 10^5 mg/L) with a vapor pressure of 7510 mm Hg at 25°C, and is expected to volatize from dry soil surfaces.

Surface Water and Ground Water Contamination - Ammonia

No data are available. Although ammonia is highly soluble in water, its rapid degradation under environmentally relevant conditions, and volatility in water and from dry soil surfaces, indicates it is unlikely to reach surface or ground waters. Ammonia is volatile in water, with EPI Suite estimated half-lives in river and lake water of 1.512 days. In wastewater treatment facilities, the half-life of ammonia is estimated as approximately 16 hours in each of the primary, aeration and settling tanks.

II. Environmental Fate Assessment – Chloramines

Busan 1215 (7.59% ammonia) is used in conjunction with sodium hypochlorite (i.e., bleach), which reacts with ammonia to form a family of microbicidal compounds called chloramines. Chloramines are formed when ammonia (NH_3) from the BUSAN 1215 reacts with chlorine from the sodium hypochlorite to produce a mixture of monochloramine (NH_2Cl), dichloramine ($NHCl_2$), and nitrogen trichloride (NCl_3). According to the manufacturer (Buckman, 2007) BUSAN 1215 is formulated specifically to achieve conditions favorable for formation of monochloramine and unfavorable for formation of other chloramines when applied according to the use instructions on the label. Further discussion on the formation of chloramines can be found in RASSB's sister reviews for environmental modeling.

Abiotic - Chloramines

None of the required guideline studies for an environmental fate assessment have been submitted. The scientific literature provides some information regarding hydrolysis, photodegradation, and decay rates in water and sediment.

Rice and Gomez-Taylor (1986) state that chloramine hydrolyzes slowly in aqueous solution. Aeration and boiling of water are not effective for the removal of chloramine; a minimal aeration loss of 10-15% has been reported for chloramine (Health Canada, 1995). A limited amount of data are available on the fate of chloramine in the environment. Monochloramine's disappearance from water is primarily a function of pH and salinity: its half-

life increases with increasing pH and decreases with increasing salinity. It decomposes more quickly if discharged into receiving waters containing bromide, presumably as a result of the formation of bromochloramine and the decomposition of the dihalamine. Monochloramine is expected to decompose via chlorine transfer to yield organic nitrogen-containing compounds in receiving waters (Jolley and Carpenter, 1983). Vikesland and colleagues (2001) stated "Unfortunately, in spite of the long history of chloramine use, the fate of chloramine in [water] distribution systems and the characteristics and processes that influence their stability are largely unknown". Chloramine half-lives in natural water range from 9 to 420 hours (Yamamoto et al., 1988). Dilute solutions of chloramine slowly decompose to form nitrogen gas, hydrochloric acid, and ammonium chloride (Vikesland et al., 2001).

Depending on the results of the hydrolysis study, a photodegradation study in water may also be needed. Ultraviolet light depletes only free chlorine, whereas chloramines seem to be quite stable in sunlight. Chloramine decay has been suggested to be at most 0.2 mg/L per sunlight hour between 10 a.m. and 2 p.m. (latitude 30–40°N) (White, 1992). Chloramine half-lives in natural water range from 9 to 420 hours (Yamamoto et al., 1988).

Decay rate constants (k) of inorganic chloramines are highly variable, varying by 4 orders of magnitude depending on the type of water used (e.g., fresh or salt water, pH, surface or deionized water, etc.), chlorine/chloramine dose, study design (e.g., in situ versus laboratory) and experimental conditions (Health Canada, 1998a). The following table summarizes study results with regard to decay rates in water and sediment.

Medium	Study Conditions	Decay Rate (per day)	Half-Life (days)	Reference
Water	Controlled conditions (no sunlight, no volatilization, 15° C) using deionized water mixed with various surface waters	0.017-0.413	1.67-40.8	Environment Canada, 1998a
Water	Deionized water with seawater mixture	0.74-1.01	0.68-0.94	Environment Canada, 1998b
Water	In Situ	144	0.005	Reckhow et al., 2000
Water	Winter and Summer	4.97 (winter), 19.54 (summer)	0.04-0.14	Wisz et al., 1978
Sediment	Sediment concentration of 5000 mg dry weight/L	0.50, 0.28, 14.83	1.4, 2.5, 0.05	Environment Canada, 1998b

Biotic - Chloramines

None of the required guideline studies for an environmental fate assessment of chloramine have been submitted. No data on biodegradation were found in the published literature.

EPI Suite Information - Chloramines

The Agency has used its databases (EPI Suite) to conduct the environmental fate risk assessment. EPI Suite estimates physical/chemical properties, environmental fate and transport, and includes estimation programs for Log K_{ow}, K_{oc}, Atmospheric Oxidation Potential, Henry's Law Constant, Water Solubility, Melting Point, Boiling Point, Vapor Pressure, Biodegradation, Bioconcentration Factor, Hydrolysis, Sewage Treatment Plant Removal, Fugacity Modeling, and Multimedia Modeling.

Chloramine (CAS No. 10599-90-3) fate properties were obtained from EPA internal environmental fate databases, open literature, and from the Estimation Programs Interface (EPI) Suite:

1. Vapor Pressure: 6.23×10^{-8} mm Hg at 25°C (modified Grain Method).
2. Henry's Law Constant (air/water partition coefficient): 6.63×10^{-5} atm-m^3/mole at 25°C.
3. K_{oc} (organic carbon ratio in soil): 14.3, mobile.
4. Log K_{ow} (octanol/water partition coefficient): -1.19.
5. The hydrolysis rate constant could not be estimated for the chemical structure of chloramine.
6. Water solubility is 1×10^6 mg/L at 25°C.
7. The reaction of vapor-phase chloramine with photochemically-produced hydroxyl radicals in the atmosphere could not be estimated due to its chemical structure.
8. The fugacity half-lives of chloramine in air, water, soil and sediment are 1×10^5 hours, 360 hours, 720 hours and 3240 hours, respectively (estimated).
9. Log BCF: 0.500; BCF: 3.162.
10. K_{oa} (octanol/air partition coefficient): 1.377.

The Henry's Law constant for chloramine indicates that it is expected to be volatile from water surfaces. The log K_{ow} (-1.19) indicates that bioaccumulation in aquatic organisms like fish is not likely, and that the soil/sediment adsorption coefficient will be low. Chloramine is highly soluble in water (1×10^6 mg/L) with a vapor pressure of 7510 mm Hg at 25°C, and is expected to volatize from dry soil surfaces.

Surface Water and Ground Water Contamination - Chloramines

A by-product of water chlorination, the reaction of ammonia compounds with chlorine is the major source of chloramine release to the environment (EPA, 1995). Rickabaugh and Kinman (1978) investigated chloramination (ammonia-chlorine process) of Ohio River water with monochloramine and found 10 mg/L, pH 7-9 and 25°C. A 1984 survey of some U.S.

utilities using chloramines as a primary disinfectant (Trussell and Kreft, 1984) showed a range of 1.5-2.5 mg/L in the distribution system.

III. Required Environmental Fate Data

As discussed above:

For three industrial water systems [***seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks (because typically control of mollusks occurs in once-through industrial water systems); and sewage and wastewater systems***], extensive environmental fate data may be required. We have assumed that the majority of residues likely to be found in effluents, and eventually surface waters, from these systems would be chloramines. However, as outlined earlier, we conclude that:

> The registrant must either: (a) submit additional extensive environmental fate, monitoring, and ecological effects data to the Agency to address the amount, extent, and duration of (presumably chloramine) residues which are being discharged in effluents and into receiving surface waters; or (b) amend the label to indicate that this product can *only be used* in these three industrial water systems when automated chloramine detection and neutralization equipment is present for detecting and neutralizing chloramines in effluents from these systems (*i.e., seawater desalination and reverse osmosis systems; seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks; and sewage and wastewater systems*). If, because of the way these three industrial water systems operate, automated chloramine detection and neutralization equipment cannot be utilized, then the data discussed under (a) above are required. (These data can be found in the attached appendix.)

Additional Environmental Fate Information for Ammonia (MRID 464581-01)

RASSB also has the following additional comments for the occurrence of ammonia in the environment. This information is taken from the Buckman Laboratories submission under the MRID No. 464581-01.

Ammonia

Ammonia occurs widely in nature. It occurs in soil, water and air. It is present as both ammonia and as the ammonium ion (NH_4^+). It does not last long in the environment because it is recycled naturally.

Ammonia exists in air at levels between 1 and 5 ppb. In air, ammonia reacts with acid air pollutants. The half life of ammonia in the atmosphere has been estimated to be a few days. Estimates of the global concentration of ammonia in air are approximately 0.6-3 ppb. This will depend on whether urban or agricultural areas are nearby.

When ammonia occurs in water under normal aerobic conditions, it is usually present as nitrate.

If ammonia is released to surface water, it can volatilize to the atmosphere. The rate of volatilization depends on the temperature and on the pH.

Uptake of ammonia by fish can also occur under certain conditions (Hargreaves 1998; Mitz and Giesy 1985).

Ammonia is present in nature as a result of organic matter decay (plants, animals, animal manure). It is also synthetically produced.

The major use of ammonia in the U.S. is as a fertilizer injected into soil.

Ammonia is a plant nutrient. It is also a part of the nitrogen cycle. Excess nitrogen is phytotoxic to plants. Ammonia is important in nitrogen metabolism because it functions as a source in the synthesis of amino acids.

Aqueous and gaseous ammonia have been used to control microbial growth in stored fruits, hay and grains.

Ammonia is adsorbed on soil. In clay, the ion tends to be adsorbed on the negative adsorption sites of clay colloids. Under anaerobic conditions, the absorptive capacity of the soil is less, resulting in the release of ammonia to either the water column or an oxidized sediment layer.

---------- Jolley, R. et al. (1978) Chlorination of Organics in Cooling Water and Process Effluents. In: Jolley, R., (ed.) Water Chlorination: Environmental Impact and Health Effects. Vol.1. Ann Arbor, MI, Ann Arbor Science Publishers, pp. 105–138. (As cited in WHO 2004).

---------- Jolley, R., J. Carpenter. (1983) A Review of the Chemistry and Environmental Fate of Reactive Oxidants in Chlorinated Water. In: Jolley, R. et al. (eds.) Water Chlorination: Environmental Impact and Health Effects. Vol. 4. Ann Arbor, MI, Ann Arbor Science Publishers, pp. 3–47. (As cited in WHO 2004).

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DATA PACKAGE BEAN SHEET

Date: 10-Mar-2008

Decision #: 380282
DP #: (342580)
PRIA
Parent DP #: 341461
Submission #: 811769

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: | Calculated Due Date: 28-Mar-2008 | Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No | Date Sent: 10-Aug-2007 | Due Back:

DP Ingredient: 005302 Ammonia

DP Title:

CSF Included: ○ Yes ● No | Label Included: ○ Yes ● No | Parent DP #: 341461

Assigned To		Date In	Date Out		
Organization	AD / RASSB	10-Aug-2007	10-Mar-2008	Last Possible Science Due Date:	07-Jan-2008
Team Name	RASSB1	10-Aug-2007	10-Mar-2008	Science Due Date:	
Reviewer Name	Gowda, Srinivas	10-Aug-2007	10-Mar-2008	Sub Data Package Due Date:	
Contractor Name					

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

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* * * Data Package Instructions * * *

Fate assmt

BUSAN 1215

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products and in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and molusks in both seawater and freshwater influent systems.

ACTIVE INGREDIENT(S)	
Ammonia (total)	**7.59%**
INERT INGREDIENTS	**92. 41%**
TOTAL	**100.00%**

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-278-0330 or 1-800-BUCKMAN for emergency medical treatment information.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

TION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. , thoroughly with soap and water after handling and before eating, drinking, chewing gum, or g tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Directions f

It is a violation of Federal law to use this product in a manner inconsis

PULP AND PAPER MILLS: BUSAN 1215 is used as a microbi contacts food.

This product is applied in conjunction with sodium hypochlorite t oxidizing microbiocide. The products are added to dilution wate 1215 to sodium hypochlorite. This ratio may be obtained by combi sodium hypochlorite (less than or equal to 15.0% wt/wt). T monochloramine solution must be generated and fed into the trea only by a trained Buckman representative. Use of this product specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product a of at least 1 ppm in excess of the system oxidant demand. Once demand rates from 50% to 80% of system demand. The product as needed to any area of the system where uniform mixing can be

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm ppm measured) as total chlorine in the water being treated for 5 to and the duration of treatment will depend on the severity of the p initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to to 15.0% wt/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm measured) as total chlorine in the water being treated on a contin treatment will depend on the severity of the problem. Badly fouled

If chloramine is detected in the effluent, it can be neutralized by the longer detected.

INDUSTRIAL WATER SYSTEMS: BUSAN 1215 is used for the c cooling towers, recirculating cooling water systems, evaporative pasteurizers, industrial fresh water systems, airwashers, seawate booth sumps, non-fish containing decorative fountains and por systems. This product is also used for the control of algae, bact influent systems.

If the effluent from a BUSAN 1215 application is discharged into a neutralization equipment will be required. If chloramine is detect sodium metabisulfite until the chloramine is no longer detected.

This product is applied in conjunction with sodium hypochlorite t oxidizing microbiocide. The products are added to dilution wate 1215 to sodium hypochlorite. This ratio may be obtained by combi sodium hypochlorite (less than or equal to 15.0% wt/wt). T monochloramine solution must be generated and fed into the trea only by a trained Buckman representative. Use of this product specified below is prohibited.

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Decision #: 380282
DP #: (342580)
PRIA
Parent DP#: 341461

DATA PACKAGE BEAN SHEE.

Date: 06-Sep-2007

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 28-Mar-2008 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Aug-2007 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: 341461

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	10-Aug-2007		Last Possible Science Due Date: 07-Jan-2008
Team Name:	RASSB1	10-Aug-2007		Science Due Date:
Reviewer Name:	Gowda, Srinivas	10-Aug-2007		Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

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* * * Data Package Instructions * * *

Fate assmt

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Pesticide Programs

January 9, 2008

MEMORANDUM

SUBJECT: Revised Environmental Exposure Assessment for Releases of BUSAN 1215 from Once-through Industrial Water Systems

From: Siroos Mostaghimi, Senior Scientist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

To: Velma Noble, PM 31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Thru: Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

DP Barcode: 34 2578

Pesticide Chemical No.: 005302

Attached please find the revised modeling report for release of BUSAN 1215 from once through industrial systems.

Introduction

This report presents and environmental exposure assessment for releases of BUSAN 1215 used for control of algae, bacteria, and fungi in once-through cooling water systems. This revised report considers the possibility of the presence of monochloramines in the water and subsequent Concentrations of Concern (COC) in effluent water. For this analysis, the Probabilistic Distribution Model (version 4) was used to estimate the number and percentage of days per year with concentrations of the BUSAN 1215 biocidal compounds exceeding ecotoxicity benchmarks of concern. The analysis was performed using the maximum BUSAN 1215 application rate as determined from the proposed amended product label. The approach used for this assessment is based on the methodology previously developed in support of the environmental exposure assessment for bromonitrostyrene (ICF, 2007).

According to the proposed amended product label, the active ingredient in BUSAN 1215 is ammonia. Therefore, Section 1 presents an environmental exposure analysis for discharges of ammonia to surface waters. However, BUSAN 1215 is used in conjunction with sodium hypochlorite (i.e., bleach), which reacts with ammonia to form a family of microbicidal compounds called chloramines. Because chloramines are the actual biocidal agents of BUSAN 1215 use, an environmental exposure assessment for chloramines is presented in Section 2. Section 3 discusses the limitations and uncertainties of the ammonia and chloramine analyses and Section 4 identifies referenced literature.

1. Environmental Exposure Assessment for Ammonia

Components of the methodology used to assess environmental exposures to ammonia include the probabalistic distribution model (PDM), BUSAN 1215 application rates, environmental exposure concentrations of concern (COCs), model facilities and flow data, and modeling scenarios.

1.1 PDM Model

PDM is a screening-level exposure assessment tool developed by EPA to model chemical releases from point sources to flowing surface waters. The PDM component within EPA's Exposure and Fate Assessment Screening Tool Version 2.0 (E-FAST2) was used for this assessment.[1]

PDM uses detailed U.S. Geological Survey (USGS) stream flow data and facility-specific data from National Pollutant Discharge Elimination System (NPDES) permits to model chemical releases from actual facilities. For a modeling period of a given number of days, PDM calculates probability distribution of the chemical concentration in the

[1] The E-FAST2 model is available from EPA at http://www.epa.gov/opptintr/exposure/pubs/efastdl.htm and documentation is available at http://www.epa.gov/opptintr/exposure/pubs/efast2man.pdf.

receiving stream, and then estimates the number of days during which the in-stream chemical concentration is expected to exceed a COC. PDM counts a day as having an exceedence of a COC if the COC is exceeded for any part of a 24-hour day. As a screening-level model, PDM outputs do not include the duration, location, or aerial extent of exceedences.

Inputs to PDM include facility NPDES number, pretreatment release (i.e., loading rate), post-treatment release, number of release days, and COCs. Input values and assumptions used for this analysis are discussed below.

1.2 BUSAN 1215 Application Rates

The proposed amended product label for BUSAN 1215 was reviewed to identify application rates for the analysis. Specific information obtained from the label included the product application rate, the percent of active ingredient (i.e., ammonia) in the product, and other product and use information needed to model ammonia concentrations surface water downstream from once-through cooling water discharges. Hereafter in this memorandum, discussion of BUSAN 1215 concentrations in cooling water and surface water refer to concentrations of BUSAN 1215 active ingredient (ai).

BUSAN 1215 is used in conjunction with sodium hypochlorite (i.e., bleach) to form a family of microbicidal compounds called chloramines. Chloramines are formed when ammonia from the BUSAN 1215 reacts with chlorine from the sodium hypochlorite to produce a mixture of monochloramine (NH_2Cl), dichloramine ($NHCl_2$), or nitrogen trichloride (NCl_3). The relative proportions of these chloramines are determined by the pH of the solution.

When chloramines come in contact with bacteria, algae, fungi, or other organic matter in the water system, the chlorine component participates in an oxidation reaction that releases the ammonia. The ammonia then is available to attach to more chlorine or to nitrify (Sloan 2007). The chemistry of these reactions is complex and dependant on several factors such as pH, temperature, relative concentrations of chlorine, ammonia, and oxidizable organic matter. A more detailed discussion of chloramine chemistry is provided in Section 2.

For the environmental exposure assessment for ammonia, it was assumed that 100 percent of the ammonia added to the cooling water in BUSAN 1215 is present in the cooling water following disinfection. It is also assumed that no ionization to NH_4^+ occurs. These assumptions overestimate actual ammonia concentrations in downstream surface water.

The BUSAN 1215 label includes directions for use of the product in industrial water systems, which include industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent waters systems, brewery and food pasteurizers, industrial fresh water systems, air washers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, and sewage and wastewater systems. Treatment instructions for these uses are summarized in Table 1.

Table 1
BUSAN 1215 Dosage Information for Industrial Water Systems

Product	Percent Active Ingredient	Label Directions	Application Rate for Analysis
BUSAN 1215	Ammonia 7.59%	When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve total chlorine residual of at least 1 ppm in excess of the system oxidant demand … mix 0.5 fluid ounces BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt).	*Continuous Treatment:* Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. *Intermittent Treatment:* Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours.

Foulant control may be achieved by either an intermittent or a continuous application of BUSAN 1215 and sodium hypochlorite solution. Both methods are intended to achieve a maximum concentration 5 ppm chlorine in the treated water, and the maximum intermittent application (i.e., 60 minutes every hour) is equivalent to continuous application. Therefore, the maximum continuous application rate was chosen as the application scenario for this analysis.

Assuming the density of sodium hypochlorite solution is 10.32 lb/gal[2], the maximum continuous use rate results in approximately 2.5 ppm by weight ai in the treated water. This application rate was calculated previously in support of a human health assessment for BUSAN 1215 (EPA, 2007). Calculation of the application rate is included in a Microsoft® Excel workbook submitted to EPA with this memorandum.

The number of release days assumed for this analysis was 250. This approach assumes that BUSAN 1215 is not applied on weekends and holidays.

1.3 Concentrations Of Concerns (COCs)

Table 2 identifies the six COCs selected for this analysis. These COCs were obtained from references provided by EPA and include two acute and four chronic toxicity endpoints for freshwater aquatic organisms. The four chronic toxicity COCs were obtained from the AWQC document for ammonia (EPA, 1999a). In particular, EPA compiled chronic EC20s for ammonia from the scientific literature to develop species mean chronic values (SMCVs).[3] Because ammonia toxicity to aquatic organisms is affected by water pH and temperature, EPA used empirical relationships to adjust the published EC20s to common conditions (i.e., pH 8 and 25°C) before calculating SMCVs. In addition, EPA presented the SMCVs in milligrams ammonia nitrogen per Liter (i.e., mg N/L), because ammonia (NH_3) partially ionizes to NH_4^+ in water. For this analysis, the SMCVs were converted to mg NH_3/L for consistency with available acute toxicity COCs and for comparison to downstream surface water concentrations predicted by the E-FAST2 model. The conversion methodology was obtained from Appendix 3 of the AWQC document for ammonia (EPA, 1999a), and the conversion calculations are included in the Excel workbook submitted to EPA with this memorandum.

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[2] Source: http://www.olinchloralkali.com/calculators/calc_naocl_convert.asp

[3] The SMCVs used for this analysis were obtained from Table 5 of the AWQC document (EPA, 1999).

Table 2
Concentrations of Concern Selected for the Environmental Exposure Assessment of BUSAN 1215 Active Ingredient (ammonia)

COC	Test Species	Endpoint Type	Study Type	Reference
88.3 µg/L	Bluegill (*Lepomis macrochirus*)	Species mean EC20	Chronic toxicity	EPA, 1999a
94.8 µg/L	Scud (*Hyalella azteca*)	Species mean EC20	Chronic toxicity	EPA, 1999a
148 µg/L	Long Fingernail Clam (*Musculium transeversium*)	Species mean EC20	Chronic toxicity	EPA, 1999a
804 µg/L	Waterflea (*Daphnia magna*)	Species mean EC20	Chronic toxicity	EPA, 1999a
117,000 µg/L	Bluegill (*Lepomis macrochirus*)	LC50	Acute toxicity to freshwater fish	Palmer et al., 2004 (MRID 464351-05)
126,000 µg/L	Rainbow trout (*Oncorhynchus mykiss*)	LC50	Acute toxicity to freshwater fish	Palmer et al., 2003 (MRID 464351-06)

Four SMCVs developed by EPA were chosen for this analysis, including the lowest values for two amphipods, a clam, and a fish species. Both of the acute COCs used for this analysis are from studies EPA classified as acceptable because they involved no significant deviations from study guideline requirements.

1.4 Modeled Facilities and Flow Data

BUSAN 1215 releases were modeled for 30 steam electric power plants (SIC 4911) that were identified by EPA during development of the exposure assessment methodology for Alkyl Dimethyl Benzyl Ammonium Chloride (Petrie and Montague, 2006). Although this sample of facilities was chosen to include a range of receiving stream flow rates and includes facilities located throughout the U.S., it is not necessarily statistically representative of all facilities with once-through cooling water systems.

Table 3 lists the stream flow data and modeled effluent discharge rates for the 30 facilities used in the analysis. The mean and 7Q10[4] flows of receiving stream reaches are available in the PDM model and were used for the analysis. Facility-specific effluent discharge rates also are available in PDM. For the analysis, the modeled effluent discharge rates were based on either facility-specific effluent discharges or the 7Q10 flows of the

[4] A 7Q10 stream flow is the lowest seven-day average stream flow over a ten year period.

receiving streams. Specifically, the modeled effluent discharge rate for each facility was the lower of these two values. The 7Q10 flow rate represents the rate that could be maintained continuously by an electric steam generating plant to ensure a steady supply of cooling water.

1.5 Results of Ammonia Discharge Modeling

PDM was run once for each facility. The numbers of days exceeding each COC were copied electronically from the PDM output files into a Microsoft® Excel workbook where averages and standard deviations were calculated. In addition, we calculated the percent of days per year above COCs. Because the number of release days per year was 250, the highest possible percent of days per year above COCs was 68 percent. We also calculated the percent of days during the release period above COCs (maximum 100 percent). Standard deviations also were calculated for all average percent of day's calculations.

The results are presented in Table 4. The table shows the average numbers of days when downstream concentrations of BUSAN 1215 active ingredient were predicted to exceed each of the COCs. The average numbers of days were calculated from the modeling results for the 30 individual facilities. Because the numbers of days with exceedences varied among the facilities, standard deviations are presented with each of the averages. Table 4 also presents the averages and standard deviations of the percentage of days-per-year and the percentage of the 250 release days with exceedences of the COCs.

For a one-year period that includes continuous releases during 250 days, the lowest COC (i.e., the chronic EC20 for bluegill, 88.3 µg/L) was exceeded on 30 percent of the days (or 44 percent of the 250 release days). COCs based on chronic toxicity to scud (*Hyalella azteca*) and the long fingernail clam (*Musculium transeversium*) were exceeded on at least 25 day per year. COCs based on acute toxicity to bluegill (*Lepomis macrochirus*) and rainbow trout (*Oncorhynchus mykiss*) were exceeded on less than one percent of the release period days and days per year. Table 5 shows the percentage of facilities that had exceedences at least once (i.e., on at least one day) for each COC. For example, the two COC based on acute toxicity were exceeded only at three (10 percent) of the 30 facilities. All other COCs were exceeded at least once at at least 67 percent of the facilities. The three lowest COCs were exceeded at least once at 26 (87 percent) of the 30 facilities.

2. Analysis of Chloramine Discharges

Section 1 evaluated environmental exposures to ammonia, the active ingredient in BUSAN 1215. As described in Section 1.2, however, disinfection is carried out by chloramines formed in solution upon application of the BUSAN 1215 according to label directions. Because chloramines have biocidal properties, this section evaluates potential environmental exposures to chloramines.

2.1 Chloramines Chemistry

Topics covered in this discussion of chlorine chemistry include the chemistry of chloramine formation, use of chloramines in disinfection, and removal of chloramines in effluent.

Table 3
Effluent Discharge and Stream Flow Data for Modeled Facilities

Facility NPDES Number	Mean Stream Flow (MGD)	7Q10 Stream Flow (MGD)	Modeled Effluent Discharge (MGD)[a]
FL0025526	401.26	263.63	117.20
GA0004341	1047.42	221.25	0.14
IA0000108	521.26	16.19	0.46
IA0033235	47.81	1.94	0.03
IL0002186	960.51	308.89	308.89
IL0036919	635.87	635.88	635.879
IL0048321	88.85	25.64	12.259
IN0032948	146.03	36.18	0.019
IN0038806	170.59	35.54	0.089
IN0041246	279.79	115.66	23.78
KS0079057	277.85	18.74	18.74
LA0003042	101.33	11.77	0.68
LA0036145	0.78	0.06	0.06
MA0004367	417.42	91.11	5.62
MI0038172	21.322	6.46	6.46
MN0000906	462.212	7.64	0.98
NC0005088	975.75	214.63	43.67
NH0001431	296.59	73.02	7.99
NM0000108	520.519	1.56	1.15
OH0010421	486.089	15.80	9.21
OK0002682	95.91	1.23	1.23
PA0002054	473.50	30.37	30.37
PA0002062	103.30	13.73	13.73
PA0008443	88.90	7.64	7.64
SC0001104	964.98	13.27	0.97
TX0001163	86.58	10.34	10.34
TX0054500	5.88	1.55	1.55
UT0000116	126.00	82.71	0.16
WA0003280	704.31	213.23	34.20
WV0005525	33.60	5.94	5.94

[a] If the effluent discharge value from PDM was less then the receiving stream 7Q10, the 7Q10 was used as the modeled effluent discharge.

Table 4
Number and Percent of Days with Downstream Ammonia Concentrations Exceeding COCs

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
88.3 µg/L	110	87	30%	24%	44%	35%
194.8 µg/L	108	87	29%	24%	43%	35%
148 µg/L	90	81	25%	22%	36%	33%
804 µg/L	28	38	8%	10%	11%	15%
117,000 µg/L	1	5	<1%	2%	<1%	2%
126,000 µg/L	1	5	<1%	2%	<1%	2%

Table 5
Percent of Facilities with Downstream Ammonia Concentrations Exceeding COCs on at Least One Day (n = 30)

COC (µg/L)	Percent of Facilities with at Least One Day with an Exceedence
88.3 µg/L	87%
194.8 µg/L	87%
148 µg/L	87%
804 µg/L	67%
117,000 µg/L	10%
126,000 µg/L	10%

2.1.1 Chloramine Formation

Chloramines, a family of microbiocidal compounds, are formed when BUSAN 1215 is used in conjunction with sodium hypochlorite (i.e., NaClO, the active component in bleach) as directed by label instructions. Chloramines are formed when ammonia (NH_3) from the BUSAN 1215 reacts with chlorine from the sodium hypochlorite to produce a

mixture of monochloramine (NH_2Cl), dichloramine ($NHCl_2$), or nitrogen trichloride (NCl_3). Monochloramine (NH_2Cl) is the preferred form of chloramine for microbiocidal purposes is NH_2Cl.

The simplified chemical equations that illustrate the formation of these three chloramines from ammonia and hypochlorite are provided in Equations 1 through 3.

$NH_3 + HOCl \rightarrow NH_2Cl + H_2O$
(Equation 1)

$NH_2Cl + HOCl \rightarrow NHCl_2 + H_2O$ (Equation 2)

$NHCl_2 + HOCl \rightarrow NCl_3 + H_2O$ (Equation 3)

Hypochlorous acid (HOCl) in these equations is formed when sodium hypochlorite is added to water. As shown in Equation 4, sodium hypochlorite readily dissociates in water to yield the hypochlorite
anion (OCl^-).

$NaClO \rightarrow Na^+ + OCl^-$
(Equation 4)

In water, OCl^- exists in equilibrium with hypochlorous acid (HOCl):

$HOCl \leftrightarrow OCl^- + H^+$ (Equation 5)

Equal amounts of HOCl and OCl^- will be present at a pH of approximately 7.5, with some variation depending on temperature. At the high pH associated with application of BUSAN 1215 according to label directions, OCl^- predominates (Edstrom Industries, 2003). Both HOCl and OCl^- are strong oxidants and together are referred to as "free chlorine" in disinfection literature. Residual chlorine existing in water in chemical combination with ammonia or organic amines is referred to as "combined chlorine." "Total chlorine" refers to the sum of free and combined chlorine (Edstrom Industries, 2003).

Equations 1 through 3 are competing reactions. The extent to which each of these reactions occurs (and the corresponding relative proportions of these chloramines) depends on the pH of the solution and the ratio of chlorine to ammonia nitrogen (Cl_2:N) present for reaction. In general, the formation of more chlorinated species is favored by a low pH and a higher Cl_2:N ratio. Monochloramine is favored at a ratio of less than 5:1 of Cl_2:N. According to the manufacturer (Buckman, 2007) BUSAN 1215 is specifically formulated to achieve conditions favorable for formation of monochloramine and unfavorable for formation of other chloramines when applied according to the use instructions on the label. For example, when BUSAN 1215 is mixed according to the directions on the submitted label (i.e., 0.5 fl. oz of product with 1 fl oz. of 15% sodium hypochlorite solution), a molar

ratio of 3:2 total dissolved ammonia to sodium hypochlorite will result. The presence of excess ammonia elevates the pH above 9, such that insignificant dichloramine and trichloramine formation will occur (Buckman, 2007).

Ammonia, the other chemical used in the formation of chloramines, is also present in water in equilibrium with a protonated weak acid, ammonium:

$$NH_4^+ \leftrightarrow NH_3 + H^+ \qquad \text{(Equation 6)}$$

The pH at which equal amounts of ammonium and ammonia are present is approximately 9.3. The forward reaction (i.e., the formation of ammonia) is favored at higher pH. Ammonia is the species required for the formation of chloramines. Therefore, the forward reaction displayed in Equation 6 is favored by the intended product formulation and use. Consequently, the formation of monochloramine (Equation 1) is favored as well. Conversion of ammonia to monochloramine at high pH is rapid and essentially complete. For example, 99 percent of ammonia in solution at pH 8.3 and 25 °C is converted to monochloramine in 0.069 seconds (White, 1999).

2.1.2 Chloramines in Disinfection

The mechanisms by which chloramines kill microorganisms are not completely understood, but are thought to involve disruption of essential proteins (e.g., viral protein coats) and protein-mediated biochemical processes like respiration (EPA, 1999b). When chloramines come in contact with bacteria, algae, fungi, or other non-living organic matter in the water system, the chlorine component participates in an oxidation reaction that consumes chlorine and releases the ammonia. The ammonia then is available to attach to more chlorine or to nitrify (Sloan, 2007). The chemistry of these reactions is complex and dependant on several characteristics of the treated waste stream, including pH, temperature, and the relative concentrations of chlorine, ammonia, and oxidizable organic matter. Therefore, chlorine disinfection typically is not performed to achieve a prescribed disinfectant dose. Instead, disinfection application is adjusted to meet the "chlorine demand." The BUSAN 1215 directions for intermittent treatment, for example, are as follows, "apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated..." Based on the chemical reactions and conditions described in Section 2.1.1, total chlorine would be expected to include HOCl, OCl-, and monochloramine, with monochloramine predominating. For comparison, the normal dosage range for monochloramine in drinking water disinfection is in the range of 1.0 to 4.0 ppm (EPA, 1999b).

2.1.3 Removal of Chloramines in Effluent

It is noted on the BUSAN 1215 label that residual chloramines detected in treated water or effluent may optionally be neutralized by the addition of sodium metabisulfite ($Na_2S_2O_5$). This reaction proceeds as shown in Equation 7 (Tchobanologous et al., 2003).

$$NaS_2O_5 + 2NH_2Cl + 3H_2O \rightarrow Na_2SO_4 + H_2SO_4 + 2Cl^- + 2NH_4^+ \quad \text{(Equation 7)}$$

The label suggests that excess sodium metabisulfite can be added until chloramines are no longer detected. The products of this reaction include ammonium ion (NH_4^+), chloride ion (Cl^-), sulfuric acid (H_2SO_4), and sodium sulfate (Na_2SO_4). If sodium metabisulfite is not utilized to neutralize chloramines in the effluent, or if neutralization is not complete, some or all of the chloramine remaining after disinfection will be present in the system effluent. Chloramines are not persistent in the environment. Once discharged, chloramines can react with oxidizable organic matter in the receiving water or spontaneously decay to nitrogen gas, hydrochloric acid, and ammonium chloride (Vikesland et al., 1998; Lewis, 1997).

2.2 Estimation of Chloramines Concentrations in Effluent

As described in Section 2.1.2, chlorine-based disinfectants, including monochloramine, are typically applied at rates adjusted to oxidative "chlorine demand" of the water to be treated. Application is controlled by monitoring the post-disinfection residual chlorine concentration and not by meeting a prescribed pre-disinfection dose concentration. According to label instructions, BUSAN 1215 is to be applied to attain a residual total chlorine concentration of no more than 5 ppm in excess of system oxidant demand. This concentration can be used to estimate the effluent monochloramine concentration for the environmental assessment.

Total residual chlorine is expected to consist primarily of HOCl, OCl-, and monochloramine, with monochloramine predominating (see Section 2.1.2). For a conservative, screening-level analysis, it is reasonable to assume that 100 percent of the 5 ppm residual chlorine is present as monochloramine. This assumption is likely to overestimate the actual percentage of monochloramine and, therefore, the concentration of monochloramine. However, the concentration may be underestimated due to the assumption that total residual chlorine does not exceed 5 ppm.

As described in Section 2.1.3, sodium metabisulfite may be added to systems treated with BUSAN 1215 to neutralize residual monochloramine. Because neutralization may or may not be performed and may or may not be completely effective at neutralizing monochloramine, the post neutralization concentration of monochloramine may range from 0 to 100 percent (i.e., 0 ppm to 5 ppm) of the assumed pre-neutralization concentration. To address this uncertainty, four assumptions are made to form four effluent concentration scenarios, as shown in Table 6.

Table 6
Monochloramine Effluent Concentration Scenarios

Scenario Number	Assumed Percentage of Monochloramine Neutralized	Concentration of Monochloramine in Effluent (ppm)
1	0%	5
2	50%	2.5
3	75%	1.25
4	100%	0

2.3 Monochloramine COCs

Table 7 identifies the seven COCs selected for this analysis. These COCs were obtained from references identified by searching the TOXNET online database.[5] The COCs were selected to include freshwater and marine species and a broad representation of aquatic biota and reported sensitivities. All COCs are from peer-reviewed sources.

2.4 Estimated Exceedence of Monochloramine COCs in Receiving Surface Waters

Results for Scenarios 1 through 3 are presented in Tables 8 through 10, respectively. Scenario 4, in which 100 percent of the monochloramine in the effluent stream is assumed to be neutralized by sodium metabisulfite, was not modeled. Tables 8 through 10 each show the average numbers of days when downstream concentrations of monochloramine were predicted to exceed each of the nine COCs. The average numbers of days were calculated from the modeling results for the 30 individual facilities. Because the numbers of days with exceedences varied among the facilities, standard deviations are presented with each of the averages.

Tables 8 through 10 also present the averages and standard deviations of the percentage of days per year and the percentage of the 250 release days with exceedences of the COCs. Figure 1 compares the percentages of release days with exceedences for the three modeled scenarios.

All three modeled scenarios resulted in exceedence of the lowest monochloramine COC (12 µg/L) on at least 63 percent of the days when BUSAN 1215 was applied. The highest monochloramine COC (2,030 µg/L) was exceeded on at least 2 percent of the days in all modeled scenarios.

[5] The TOXNET database may be accessed at: http://toxnet.nlm.nih.gov/

Table 7
Concentrations of Concern Selected for the Environmental Exposure Assessment of Monochloramine

COC	Test Species	Endpoint Type	Species Habitat	Reference
12 µg/L	*Ceriodaphnia dubia* (Water flea)	LC50	Freshwater	Taylor (1993)
350 µg/L	*Notropis atherinoides* (Emerald shiner)	LC50	Freshwater	Brooks and Seegert (1978)
560 µg/L	*Homarus americanus* (American lobster, stage 1 larvae)	LC50	Marine	Capuzzo et al. (1976)
570 µg/L	*Cynoscion nebulosus* (Spotted seatrout, 10 hr old eggs)	LC50	Estuarine/Marine	Johnson et al. (1977)
650 µg/L	*Ictalurus punctatus* (Channel catfish)	LC50	Freshwater	Brooks and Seegert (1978)
1,230 µg/L	*Lepomis macrochirus* (Bluegill sunfish)	LC50	Freshwater	Brooks and Seegert (1978)
2,030 µg/L	*Gambusia affinis* (Western mosquito fish)	LC50	Freshwater (euryhaline)	Cherry et al. (1982)

With Scenario 1, in which 100 percent of the post-treatment monochloramine is conservatively assumed to be discharged, the average percentage of release day with downstream monochloramine concentrations above COCs ranged from 11 percent for the highest COC (2,030 µg/L) to 75 percent for the lowest COC. When 75 percent of the post-treatment monochloramine was assumed to be neutralized with sodium metabisulfite, the percentage of days with exceedences ranged from 2 percent to 63 percent for the highest and lowest COCs, respectively.

As shown in Figure 1, the three modeled scenarios resulted in similar relationships between the percentage of days with exceedednces and increases in COC.

Table 8
Number and percent of Days with Downstream Monochloramine Concentrations Exceeding COCs – Scenario 1

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
12	187	89	51%	25%	75%	36%
350	88	85	24%	23%	35%	34%
560	72	81	20%	22%	29%	32%
570	71	81	19%	22%	28%	32%
650	66	79	18%	22%	27%	31%
1,230	44	63	12%	17%	18%	25%
2,030	28	44	8%	12%	11%	18%

Scenario 1: Concentration of monochloramine in effluent is 5 ppm continuously for 250 days.

Table 9
Number and percent of Days with Downstream Monochloramine Concentrations Exceeding COCs – Scenario 2

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
12	174	94	48%	26%	70%	38%
350	67	78	18%	21%	27%	31%
560	49	67	13%	18%	20%	27%
570	49	66	13%	18%	19%	26%
650	44	61	12%	17%	18%	24%
1,230	23	38	6%	10%	9%	15%
2,030	13	23	4%	6%	5%	9%

Scenario 2: Concentration of monochloramine in effluent is 2.5 ppm continuously for 250 days.

Table 10
Number and percent of Days with Downstream Monochloramine Concentrations Exceeding COCs – Scenario 3

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
12	157	96	43%	26%	63%	38%
350	41	58	11%	16%	16%	23%
560	26	41	7%	11%	10%	16%
570	25	40	7%	11%	10%	16%
650	22	37	6%	10%	9%	15%
1,230	10	18	3%	5%	4%	7%
2,030	5	9	1%	3%	2%	4%

Scenario 3: Concentration of monochloramine in effluent is 1.25 ppm continuously for 250 days.

3. Limitations and Uncertainties

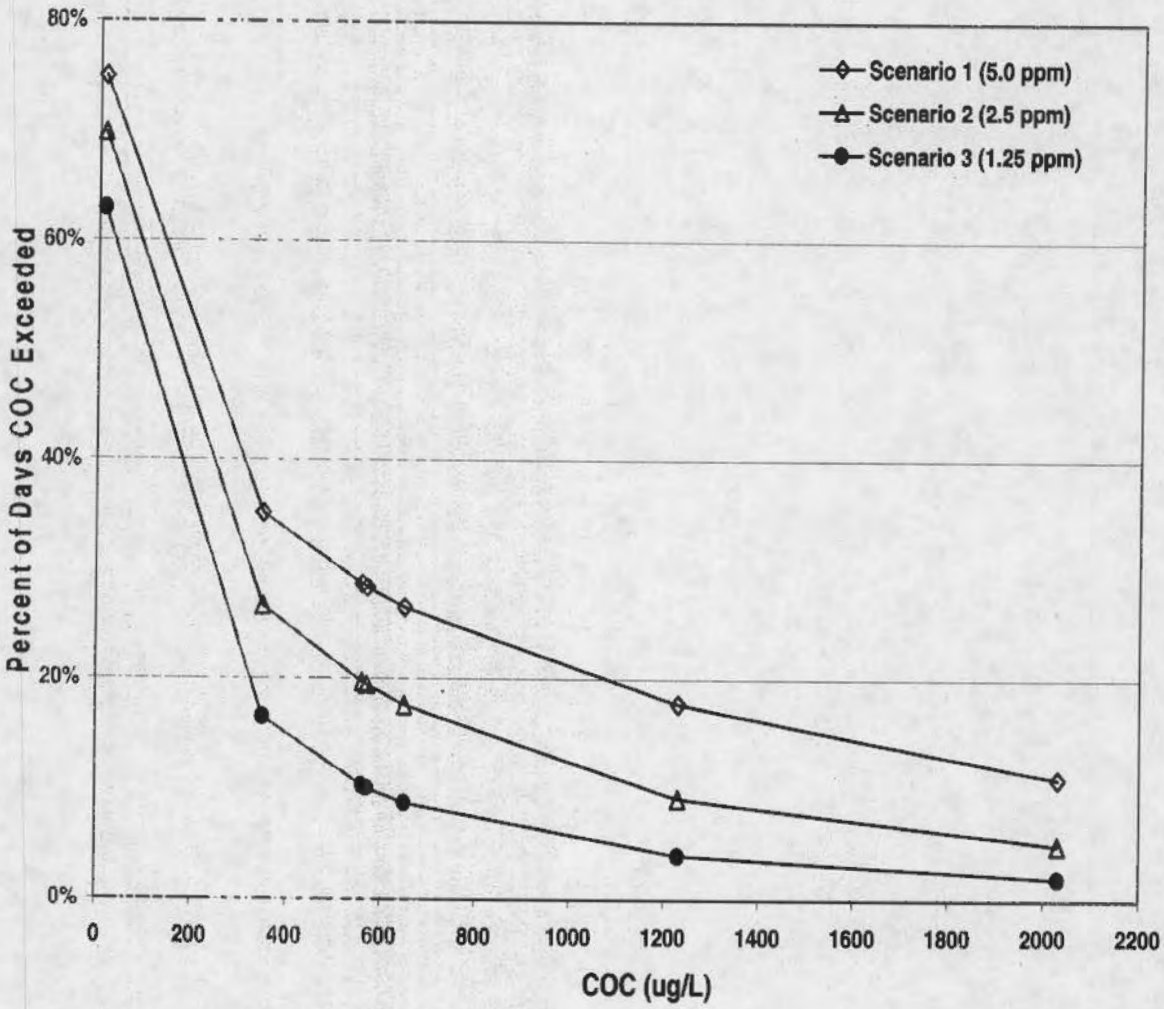
This analysis is a screening level evaluation of the potential for discharges from once-through cooling water systems to exceed ecotoxicity COCs for BUSAN 1215 active ingredient (ammonia) and monochloramine in receiving streams. The methodology involves the following potential limitations:

- For the ammonia analysis, the effects of pH, temperature, and water chemistry on ammonia ionization and chloramine formation are not addressed in the methodology. Instead, we assumed that application of BUSAN 1215 and sodium hypochlorite according to label instructions results sufficient chloramine for effective disinfection and that the oxidation reactions that occur during disinfection release 100 percent of the ammonia back into the water. It is also assumed that no ionization to $NH4^+$ occurs. These assumptions overestimate actual ammonia concentrations in downstream surface water.

- All ammonia, chlorine, and monochloramine are assumed to originate with the addition of BUSAN 1215 and sodium hypochlorite. That is, it is assumed that

there are no background concentrations of these chemicals in the pre-treatment effluent stream of the receiving surface waters.

Figure 1. Average Percent of Release Days with Downstream Monochloramine Concentration above COCs



- Ammonia and monochloramine in the effluent is assumed not to react (e.g., with suspended organic matter in the receiving water body) between the point of discharge and the point of ecological exposure.

- The analysis used flow and discharge data for a sample of 30 steam electric generating facilities. This sample is not necessarily statistically representative of the national population of facilities with once-through cooling water systems where BUSAN 1215 may be used.

- The 30 steam electric generating facilities modeled for this analysis are not necessarily representative of other types of facilities were industrial water uses of BUSAN 1215 are proposed: recirculating cooling water systems, evaporative condensers, influent waters systems, brewery and food pasteurizers, industrial fresh water systems, air washers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, and sewage and wastewater systems.

- Because exceedences predicted by the PDM do not necessarily occur on consecutive days the analysis may overestimate the actual potential for ecological toxicity impacts. The numbers of days with exceedences of COCs have not been compared to the numbers of days of exposure used in the studies from which the COCs were obtained.

- Downstream concentrations of ammonia or monochloramine are considered to exceed a COC on any given day if the COC is exceeded for any portion of the day. PDM does not identify the duration of the exceedences, and the daily scale results may overestimate the actual potential for ammonia or monochloramine releases to result in ecological risks.

- The estimated numbers of days with downstream concentrations ammonia or monochloramine above COCs are average calculated from the results for individual facilities. Facility level results varied considerably, as shown by the standard deviations presented with the averages. Thus, this analysis may under or overestimate the potential for the exceedences at specific facilities.

- The analysis used an assumed release period of 250 days. This assumption is likely to overestimate the number of release days for BUSAN 1215 treatment, especially for initial control. Thus, the results of the analysis may overestimate the number of days with downstream ammonia or monochloramine concentrations above COCs.

- The release scenarios for the ammonia and monochloramine analyses were based on the maximum application rate based on product labels. It may be possible to control of target organisms with application rates below the maximum. In addition,

continuous dosing was assumed throughout the release period. This assumption may overestimate the daily treatment duration that would be required for effective control.

- For this analysis, effluent discharge rates were assumed to equal the lower of either facility-specific effluent flow rates or the 7Q10 flows of the receiving streams. This approach may over or underestimate average actual effluent discharges.

- Ammonia COCs for chronic toxicity to aquatic organisms are based on SMCVs calculated by EPA. These species means are higher than the most conservative reported values reported. In addition, the SMCVs may be affected by uncertainties and limitations associated with the original studies and methods developed by EPA to convert reported values to a common water pH and temperature.

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CC: RASSB Chemical Files
Siroos Mostaghimi, RASSB

DATA PACKAGE BEAN SHEET

Date: 10-Mar-2008

Decision #: 380282
DP #: (342578)
PRIA
Parent DP #: 341461
Submission #: 811769

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: Calculated Due Date: 28-Mar-2008 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Aug-2007 Due Back:

DP Ingredient: 005302, Ammonia

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: 341461

Assigned To	Date In	Date Out	
Organization AD / RASSB	10-Aug-2007	10-Mar-2008	Last Possible Science Due Date: 07-Jan-2008
Team Name RASSB1	10-Aug-2007	10-Mar-2008	Science Due Date:
Reviewer Name Mostaghimi, Siroos	10-Aug-2007	10-Mar-2008	Sub Data Package Due Date:
Contractor Name:			

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

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DATA PACKAGE BEAN SHEET

Date: 10-Mar-2008

Decision #: 380282
DP #: (342578)
PRIA
Parent DP #: 341461
Submission #: 811769

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: Calculated Due Date: 28-Mar-2008 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7 59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Aug-2007 Due Back:

DP Ingredient: 005302, Ammonia

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: 341461

Assigned To		Date In	Date Out	
Organization	AD / RASSB	10-Aug-2007	10-Mar-2008	Last Possible Science Due Date: 07-Jan-2008
Team Name	RASSB1	10-Aug-2007	10-Mar-2008	Science Due Date:
Reviewer Name	Mostaghimi, Siroos	10-Aug-2007	10-Mar-2008	Sub Data Package Due Date:
Contractor Name				

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No Studies

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DATA PACKAGE BEAN SHEET

Date: 06-Mar-2008

Decision #: 380282

DP #: (341461)

PRIA

Parent DP#:

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Drusilla Copeland DCOPELAN

Sent Date: Calculated Due Date: 28-Mar-2008 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 11-Jul-2007 Due Back:

DP Ingredient: 005302, Ammonia

DP Title:

CSF Included: ◯ Yes ● No Label Included: ● Yes ◯ No Parent DP #:

Assigned To	Date In	Date Out	
Organization: AD / RASSB	26-Jul-2007	06-Mar-2008	Last Possible Science Due Date: 07-Jan-2008
Team Name: RASSB1	26-Jul-2007	06-Mar-2008	Science Due Date:
Reviewer Name: Mostaghimi, Siroos	26-Jul-2007	06-Mar-2008	Sub Data Package Due Date:
Contractor Name:			

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No Studies

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Norm: NEW USE - Please conduct a risk assessment. No data was submitted. New label, Data matrix.

Decision #: 380282
DP #: (342580)
PRIA
Parent DP#: 341461

DATA PACKAGE BEAN SHEET

Date: 15-Feb-2008

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 28-Mar-2008 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Aug-2007 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: 341461

Assigned To		Date In	Date Out		
Organization:	AD / RASSB	10-Aug-2007		Last Possible Science Due Date:	07-Jan-2008
Team Name:	RASSB1	10-Aug-2007		Science Due Date:	
Reviewer Name:	Gowda, Srinivas	10-Aug-2007		Sub Data Package Due Date:	
Contractor Name:					

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No Studies

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Fate assmt

Decision #: 380282
DP #: (342581)
PRIA
Parent DP#: 341461

DATA PACKAGE BEAN SHEET

Date: 15-Feb-2008

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 28-Mar-2008 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Aug-2007 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: 341461

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	10-Aug-2007		Last Possible Science Due Date: 07-Jan-2008
Team Name:	RASSB1	10-Aug-2007		Science Due Date:
Reviewer Name:	Gowda, Srinivas	10-Aug-2007		Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

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Eco assmt

[redacted]ITED STATES ENVIRONMENTAL PRO[redacted]TION AGENCY
WASHINGTON, D.C. 20460

June 15, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
OR PAY ON-LINE at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-380282
EPA File Symbol or Registration Number: 1448-433
Product Name: BUSAN 1215
EPA Receipt Date: 11-Jun-2007
EPA Company Number: 1448
Company Name: BUCKMAN LABORATORIES INC

DENNIS BARBEE
BUCKMAN LABORATORIES INC
1256 NORTH MCLEAN BLVD
MEMPHIS, TN 38108

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A50

NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Please remit payment in the amount of: $ 10,500 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is soley associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900 Potomac Yard
2777 S. Crystal Dr.
Arlington, VA

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman,

at (703) 308-6432.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

U. ED STATES ENVIRONMENTAL PROTE. .ION AGENCY
WASHINGTON, D.C. 20460

February 14, 2008

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

SUBJECT: Occupational Exposure Assessment for the new proposed use of BUSAN 1215 in Industrial Water Systems

From: Siroos Mostaghimi, Senior Scientist Siroos - Mostaghimi
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

To: Velma Noble, PM 31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Thru: Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

DP Barcode: 341461

Pesticide Chemical No.: 005302

EPA Reg. No. :14480-433

Action Requested:

Risk Assessment and Science Support Branch (RASSB) has been requested to conduct an occupational exposure for the proposed new use of the BUSAN 1215.

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For BUSAN 1215 the criterion is not met because of the nature of the delivery of the product, which is in a closed system. Therefore, this report presents a qualitative assessment for this new use.

According to the label submitted by the Buckman Laboratories International Inc., Busan 1215 which contains 7.59% ammonia is used to control algal, bacterial and fungal deposits in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwshers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. The label also indicates that this product is used for bacteria, algae and fungi control in both seawater and freshwater influent systems.

Recommendations:

The method of the delivery for the new use of BUSAN 1215 is similar to use for pulp and paper mill process water systems which was reviewed by RASSB scientist, Doreen Aviado in a memorandum to Dennis Edward dated January 30, 2006, titled "Occupational exposure considerations for proposed industrial end-use product BUSAN 1215: new use pattern for the active ingredient ammonia in pulp and paper mill process water systems". RASSB has the following recommendation for the use of the BUSAN 1215 in industrial water systems:

1. The label submitted by the registrant does not indicate clearly that the delivery of the chemical is in a closed system. RASSB assumes that Buckman trained technicians will set up the initial delivery system and other plant workers are not involved in this process. The label should be reworded to clearly state that the closed delivery system will be set up by the trained technicians. If this is not the case, RASSB will revisit the request for this new application and may require additional data and or revisions to the label.
2. RASSB also recommends that all the requirements stated in Aviado's memorandum in regard to the use of BUSAN 1215 in pulp and paper mill process water systems is applicable and should be followed for the use of BUSAN 1215 in industrial water systems(A copy of the memorandum is attached to this report).

File: C:\MyFiles\2007 Reports\BUSAN1215\ Application and Post-Application Worker Exposure Assessment for the Proposed New Uses of Busan 1215 in Industrial Water Systems

CC: RASSB Chemical Files
Siroos Mostaghimi/RASSB

Appendix

Doreen Aviado memorandum to Dennis Edwards

Decision #: 380282

DATA PACKAGE BEAN SHEET

DP #: (342577)

Date: 14-Feb-2008

PRIA

Parent DP#: 341461

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 28-Mar-2008 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 10-Aug-2007 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: 341461

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	10-Aug-2007	14-Feb-2008	Last Possible Science Due Date: 07-Jan-2008
Team Name:	RASSB1	10-Aug-2007	14-Feb-2008	Science Due Date: _____
Reviewer Name:	Tao, Jenny	10-Aug-2007	14-Feb-2008	Sub Data Package Due Date: _____
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Tox endpoints

DP#: (342577) *** Additional Data Package for this Decision *** Decision#: (380282)

DP #	Division/Branch	[illegible]	[illegible]	Instructions?	DCI	Label
341461	AD / RMB1	11-Jul-2007	07-Jan-2008	Yes No	Yes No	Yes No
341461	AD / RASSB	11-Jul-2007	07-Jan-2008	Yes No	Yes No	Yes No
342578	AD / RASSB	10-Aug-2007	07-Jan-2008	Yes No	Yes No	Yes No
342578	AD / RASSB	10-Aug-2007	07-Jan-2008	Yes No	Yes No	Yes No
342580	AD / RASSB	10-Aug-2007	07-Jan-2008	Yes No	Yes No	Yes No
342580	AD / RASSB	10-Aug-2007	07-Jan-2008	Yes No	Yes No	Yes No
342581	AD / RASSB	10-Aug-2007	07-Jan-2008	Yes No	Yes No	Yes No
342581	AD / RASSB	10-Aug-2007	07-Jan-2008	Yes No	Yes No	Yes No

Decision #: 380282

DATA PACKAGE BEAN SHEET

DP #: (342578)

Date: 15-Feb-2008

PRIA

Parent DP#: 341461

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 28-Mar-2008 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Aug-2007 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: 341461

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	10-Aug-2007		Last Possible Science Due Date: 07-Jan-2008
Team Name:	RASSB1	10-Aug-2007		Science Due Date:
Reviewer Name:	Mostaghimi, Siroos	10-Aug-2007		Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Env modeling

DATA PACKAGE BEAN SHEET

Date: 15-Feb-2008

Decision #: 380282

DP #: (342577)

PRIA

Parent DP#: 341461

* * * Registration Information * * *

Registration: 1448-433 - BUSAN 1215

Company: 1448 - BUCKMAN LABORATORIES INC

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Norman Cook NCOOK

Sent Date: _____ Calculated Due Date: 28-Mar-2008 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 005302, Ammonia(7.59%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 10-Aug-2007 Due Back: _____

DP Ingredient: 005302, Ammonia

DP Title: _____

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: 341461

Assigned To		Date In	Date Out	
Organization:	AD / RASSB	10-Aug-2007	14-Feb-2008	Last Possible Science Due Date: 07-Jan-2008
Team Name:	RASSB1	10-Aug-2007	14-Feb-2008	Science Due Date: _____
Reviewer Name:	Tao, Jenny	10-Aug-2007	14-Feb-2008	Sub Data Package Due Date: _____
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Tox endpoints

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 13, 2008

MEMORANDUM

SUBJECT: **Ammonia (BCMW/Busan 1215)**: Toxicology Review of Proposed New Use in Industrial Water Systems

DPA Reg. No.: 14480-433
PC Code: 005302
DP Barcode: D342577

FROM: Jenny J. Tao
Toxicologist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

TO: Dennis Edwards, Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)

THROUGH: Nader Elkassabany, Team Leader 2/14/08
Team Two
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

and

Norm Cook, Chief 2/14/08
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

I. ACTION REQUESTED

Review human health toxicity of ammonia for proposed new uses in industrial water systems.

II. BACKGROUND

The registrant, Buckman Laboratories International, Inc., has submitted an amendment for the product Busan 1215 (aka BCMW) to add a new use in industrial water systems. Busan 1215 is an [redacted], which is applied in conjunction with sodium hypochlorite (at a minimum of 1:1 molar ratio) to form monochloramine according to the amended label. The registrant proposes to use Busan 1215 in controlling algae, bacteria and fungi in "industrial cooling towers, recirculation cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems." Busan 1215 is also intended to be used in both seawater and freshwater influent systems to control algae, bacteria, fungi and mollusks.

Busan 1215 can be used in intermittent or continuous treatment, by mixing 0.5 fluid ounces of Busan 1215 with 1.0 fluid ounces of sodium hypochlorite (up to 15% wt/ml) to achieve a total chlorine residual of at lease 1 ppm in excess of the system oxidant demand. A total chlorine residual of 1 to 2 ppm for intermittent treatment and 0.5 to 1 ppm for continuous treatment is needed; the maximum total chlorine residual is 5 ppm in water for both intermittent and continuous treatment. The frequency and duration of the treatment vary depending upon the severity of the situation. Generally the water is treated for 5 to 60 minutes every 1 to 6 hours. An initial cleanup before treatment should be carried out for badly fouled systems.

III. RESULTS AND DISCUSSION

1. Acute Toxicity of Busan 1215

The acute toxicity data for the product Busan 1215 containing 7.59% of ammonia are acceptable. All of the acute toxicity studies for Busan 1215 are classified as category IV, and Busan 1215 is a non-sensitizer. The acute toxicity data on Busan 1215 is summarized below in Table 1.

Table 1. Acute Toxicity Data on Busan 1215

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity	46435108	$LD_{50} > 5000$ mg/kg	IV
870.1200 Acute dermal toxicity	46435109	$LD_{50} > 5000$ mg/kg	IV
870.1300 Acute inhalation toxicity	46435110	$LC50 \geq 2.08$ mg/L (4-hr)	IV
870.2400 Acute eye irritation	46435111	Minimally irritating (rabbit) Irritation cleared within 48 hours	IV
870.2500 Acute dermal irritation	46435112	Slightly irritating	IV
870.2600 Skin sensitization	46435113	Not a skin sensitizer (guinea pig)	N/A

N/A – not applicable

2. Ammonia Toxicity Profile

The Agency conducted a hazard assessment of ammonia for use in food-contact pulp/paper products in December 2005 (D3113637); detailed discussion of ammonia toxicity can be found in this document. A summary of its toxicity is provided below.

Ammonia is a corrosive substance, and the main toxic effects of acute toxicity are restricted to the sites of direct contact with ammonia (i.e., skin, eyes, respiratory tract, mouth, and digestive tract). It is an upper respiratory irritant in humans. Immediate nose and throat irritation is experienced at concentrations exceeding 50 ppm, and immediate lethality may occur at concentrations in excess of 5,000 ppm; however, the acute lethal concentration depends on the exposure duration.

The skin is extremely sensitive to airborne ammonia or ammonia dissolved in water. Dermal exposures to liquid ammonia or concentrated solutions and/or ammonia gas are frequently occupationally related and produce cutaneous burns, blisters, and lesions of varying degrees of severity. The severity of the damage is proportional to the concentration and duration of exposure; flushing with water immediately after contact alleviates or prevents effects.

Ingestion of concentrated ammonium solutions may produce severe burns and hemorrhage of the upper gastrointestinal tract.

Ammonia caused adverse respiratory effects in animals following inhalation exposure. In F344 rats (6/sex/dose) continuously to 25, 50, 150 or 250 ppm ammonia (HEC = 1.9, 3.7, 11.2 or 18.6 mg/m^3, respectively) for 7 days prior to inoculation with Mycoplasma pulmonis and from 28-42 days following M. pulmonis exposure (in order to produce murine respiratory mycoplasmosis [MRM]), all levels of ammonia, whether produced naturally or derived from a purified source, significantly increased the severity of rhinitis, otitis media, tracheitis and pneumonia characteristic of M. pulmonis. Furthermore, there was a significant concentration response between observed respiratory lesions and increasing environmental ammonia concentration for gross and microscopic lesions. All lesions observed were characteristic of MRM. Gross bronchiectasis and/or pulmonary abscesses and the extent of gross atelectasis and consolidation were consistently more prevalent in exposed animals at all concentrations than in their corresponding controls. The severity of the microscopic lesions in the nasal passages, middle ears, tracheas and lungs was significantly greater in all exposed groups compared with controls. Increasing ammonia concentration was not associated with an increasing frequency of M. pulmonis isolations. Additionally, rats not exposed to M. pulmonis and exposed to ammonia at 250 ppm developed nasal lesions (epithelial thickening and epithelial hyperplasia) unlike those observed in inoculated rats. Based upon these data in M. pulmonis exposed rats, a LOAEL (HEC) of 1.9 mg/m^3 was identified.

Other adverse respiratory effects, which were concentration- and time-dependent, were seen in respiratory tract in rats, guinea pigs, mice and chickens. These adverse effects included, but not limited to, a mucilaginous exudate, acute inflammatory reactions with infiltration of neutrophils, large mononucleated cells, monocytes and immature fibroblasts in the trachea, hyperplasia of the tracheal epithelium, necrotic changes at the luminal surface (pyknotic nuclei and karyorrhectic cells) of the trachea, darkening/reddening, edema, congestion, and hemorrhage in the lungs. Ophthalmological changes, such as clouding of the cornea and corneal opacities, were also observed in chickens.

No developmental or reproductive studies have been conducted by the registrant for ammonia.

No neurotoxicity studies have been conducted by the registrant. Studies in the scientific literature indicate that neurological effects have been observed in humans following inhalation and dermal exposure. These effects have been limited to blurred vision, most likely due to direct contact, but more severe exposures, which result in significant elevation of blood ammonia levels (hyperammonemia) can result in diffuse nonspecific encepthalopathy, muscle weakness, decreased deep tendon reflexes and loss of consciousness.

A few studies on the genotoxicity of ammonia suggest that ammonia and ammonia ion may have clastogenic and mutagenic properties. Ammonia has not been classified for carcinogenic effects by the Agency, the Department of Health and Human Services (DHHS), or the International Agency for Research on Cancer (IARC).

Chronic occupational exposure to low levels of airborne ammonia (< 25 ppm) had little effect on pulmonary function or odor sensitivity in workers at some factories, but studies of farmers exposed to ammonia and other pollutants in livestock buildings indicated an association between exposure to pollutants, including ammonia, and an increase in respiratory symptoms and/or decrease in lung function parameters. The contribution of ammonia to these respiratory symptoms is unclear.

USEPA (2005) established an inhalation reference concentration (RfC) based on both an occupational study and an animal toxicity study to be protective of respiratory effects. A no-observable-adverse effect level (NOAEL) of 6.4 mg/m^3 (9.2 ppm) from an occupational study was combined with a lowest observable adverse effect level (LOAEL) of 17.4 mg/m^3 (25 ppm), which has a human equivalent concentration (HEC) of 1.9 mg/m^3, for respiratory effects in a rat subchronic inhalation study. The Agency acknowledges that certain database deficiencies exist including a lack of adequate reproductive and developmental toxicology studies for ammonia in the IRIS record; an additional 3X factor is applied to account for these deficiencies.

3. Toxicity Endpoint Selection

3.1. Occupational Exposure to Ammonia

3.1.1 Dermal Exposure (all durations)

No endpoint was selected because the labels will specify the use of gloves, full body clothing and eye protection. Thus, there is no potential concern for dermal exposure.

3.1.2 Inhalation Exposure (all durations)

Study Selected: Holness et al. (1989), occupational study of workers

Executive Summary: Holness et al. investigated production workers exposed to ammonia in a soda ash facility. All of the available 64 production workers were invited to participate and 82% agreed to be evaluated. The control group consisted of 31 other plant workers from stores and office areas of the plant without previous exposure to ammonia. The mean age of the workers was 38.9 years and duration of exposure was 12.2 years. Weight was the only statistically significant difference in demographics

found after comparing height, weight, years worked, % smokers and pack-years smoked. The mean TWA ammonia exposures based on personal sampling over one work shift (average sample collection 8.4 hours) of the exposed and control groups were 9.2 ppm (6.4 mg/m^3) and 0.3 ppm (0.21 mg/m^3), respectively.

A questionnaire was administered to obtain information on exposure and work histories and to determine eye, skin and respiratory symptomatology (based on the American Thoracic Society [ATS] questionnaire [Ferris, 1978]). Spirometry (FVC, FEV-1, FEF50 and FEF75) was performed according to ATS criteria at the beginning and end of each work shift on the first workday of the week (day 1) and the last workday of the week (day 2). Differences in reported symptoms and lung function between groups were evaluated using the actual values and with age, height and pack-years smoked as covariates in linear regression analysis. Baseline lung function results were expressed as percent of predicted values calculated from Crapo et al. (1981) for FVC and FEV-1 and from Lapp and Hyatt (1967) for FEF50 and FEF75.

No statistical difference in the prevalence of the reporting symptoms was evident between the exposed and control groups, although workers reported that exposure at the plant had aggravated specific symptoms including coughing, wheezing, nasal complaints, eye irritation, throat discomfort and skin problems. The percentage of exposed workers reporting hay fever or familial history of hay fever was significantly less than controls, suggesting possible self-selection of atopic individuals out of this work force. The atopic status of the worker and control groups was not determined by skin prick tests to common aeroallergens. Furthermore, the workers complained that their symptomatology was exacerbated even though there was no statistical difference between groups. Since the study was cross-sectional in design with a small population, it is possible that selection bias may have occurred.

Baseline lung functions (based on the best spirometry values obtained during the four testing sessions) were similar in the exposed and control groups. No changes in lung function were demonstrated over either work shift (days 1 or 2) or over the workweek in the exposed group compared with controls. No relationship was demonstrated between chronic ammonia exposure and baseline lung function changes either in terms of the level or duration of exposure, probably due to lack of adequate exposure data for categorizing exposures and thus precluding development of a meaningful index accounting for both level and length of exposure.

Based on the lack of subjective symptomatology and changes in spirometry, this study establishes a free-standing TWA NOAEL of 9.2 ppm (6.4 mg/m^3). Adjustment for the TWA occupational scenario results in a NOAEL (HEC) of 2.3 mg/m^3.

Dose and Endpoint for Risk Assessment: The 8-hour TWA NOAEL of 9.2 ppm (6.4 mg/m^3) was selected based on lack of evidence of decreased pulmonary function or changes in subjective symptomatology in the occupational study. The 24-hour adjusted NOAEL is 2.3 mg/m^3. This 24-hour NOAEL is the basis of the Agency's inhalation reference concentration (RfC) presented on the Integrated Risk Information System (IRIS) and represents Agency consensus (USEPA 2005).

Margin of Exposure for Occupational Exposure: For all durations, a MOE of 30 is adequate.

Comments about Study/Endpoint/Margins of Exposure: An uncertainty factor of 30 (UF = 30) is determined, where 10x is used to allow for the protection of sensitive individuals (intra-species extrapolation). Because it is based on a human occupational study, no inter-species safety factor is required. A factor of 3x was used to account for several data base deficiencies including the lack of chronic data and the lack of reproductive and developmental toxicology studies.

A summary of toxicological doses and endpoints selected for ammonia is shown in Table 2.

Table 2: Summary of Toxicological Doses and Endpoint Selection for Ammonia

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern (LOC) for Risk Assessment	Study and Toxicological Effects
Dermal (all durations) (Occupational)	Not selected. Labels will specify the use of gloves, full body clothing and eye protection.		
Inhalation (all durations) (Occupational)	8-hr TWA NOAEL = 6.4 mg/m^3 (9.2 ppm) 24-hr adjusted NOAEL (HEC) = 2.3 mg/m^3 UF = 30 (10x for intraspecies extrapolation and 3x for database deficiencies)	LOC for MOE = 30	Occupational Study (Holness et al., 1989) LOAEL = none Lack of evidence of decreased pulmonary function or changes in subjective symptomatology See IRIS record (USEPA 2005) for more detailed discussion.

TWA = time-weighted-average, UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, HEC= human equivalent concentration

The proposed use of Busan 1215 in industrial water systems is considered an indoor non-food use. There may be potential inhalation concern for occupational exposure to ammonia for the proposed new use, assuming that proper worker's protection will be applied. Based on the Registrant statement, Busan 1215 is to be mixed with sodium hypochlorite through a chemical feed system, and a diagram and direction included suggesting a closed-system operation (pages 20 and 24 of the Supplemental Report: Mammalian Toxicology and Environmental Fate and effects Data). It is indicated that Busan 1215 is transported through semi-bulk transfer tote bins, which are specifically designed to be connected directly to a "base" tote feed container. Busan 1215 is introduced to a treatment water system via a chemical feed skid to allow the introduction of Busan 1215 to a pipe where continuous flow through dilution water is available. In addition, the Registrant indicates that proper personal protective equipment (PPE) is required during the operation. It should be noted that in order to be qualified as a closed-system application for hazard and human exposure assessment, the Registrant needs to clearly specify the uses in such manner in the amended label. In addition, the Registrant needs to revise the label to include the requirement of using proper worker's protection (gloves, full-body clothing and eye protection, etc.).

IV. CONCLUSIONS

RASSB agrees that the concerns for hazard and human exposure from the proposed use of Busan 1215 in industrial water systems may be minimal, if it is used in a closed-system operation. RASSB recommends that the label be revised to specify the uses are in a closed loading and delivery system and to include the requirement of using proper worker's protection when applying Busan 1215 to minimize human exposures from the use.

V. REFERENCES

Busan 1215. Amended Product Label. Buckman Laboratories, Inc., Memphis, Tennessee.

Smegal, D to Copeland, D. 2005. Memorandum: Hazard Assessment for Ammonia and Monochloroamine. December 9, 2005. D313637.

USEPA, 2005. Integrated Risk Information System for Ammonia. http://www.epa.gov/iris/subst/o422.htm.

Watson, CF. 2005. Supplemental Report: Mammalian Toxicology and Environmental Fate and Effects Data. Buckman Laboratories International, Inc. January 20, 2005.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

January 30, 2006

MEMORANDUM

SUBJECT: Occupational Exposure Considerations for Proposed Industrial End-Use Product ***BUSAN 1215***: New Use Pattern for the Active Ingredient **Ammonia** in Pulp and Paper Mill Process Water Systems.

TO: Dennis Edwards, Chief
Velma Noble, Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Doreen Aviado, Biologist
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

THRU: Kathryn Montague, Acting Team Leader
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

DP Barcode: D313640

Pesticide Chemical/No.: Ammonia / 005302

Registrant: Buckman Laboratories, Inc.

EPA File Symbol(s): 1448-UGE: *BCMW* (MUP for Formulator Use)

Action Requested:

The Antimicrobials Division (AD), Product Management Team 31, requested that the Risk Assessment and Science Support Branch (RASSB) conduct an occupational exposure assessment in support of the proposed industrial end-use product *BUSAN 1215* (EPA File Symbol 1448-UGG) containing 7.59% ammonia (total) as the active ingredient. Ammonia is currently registered as an active ingredient at 0.2% in only one product, AANKILL 44 (EPA Reg. No. 63709-1), an insecticide against fire ants. Therefore, the proposed industrial use of *BUSAN 1215* to control algal, bacterial and fungal deposits in pulp/paper mill process water systems constitutes a "new use" for the active ingredient.

An exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For *BUSAN 1215,* toxicological hazard has been identified for ammonia concentrates as acute dermal corrosivity and irritation to the respiratory system. Protecting occupational workers against dermal/eye injury and respiratory tract/mucosal damage from off-gassing of ammonia vapor (due to its high vapor pressure) is of particular concern for workplace safety. However, the exposure criterion is not met since proposed use conditions [closed-system delivery, personal protective equipment (PPE), industrial safety guidelines for monitoring of airborne ammonia] will negate any contact with ammonia in the workplace. Therefore, only a "qualitative" assessment is presented to address potential occupational (handler and postapplication) exposures from use of *BUSAN 1215* in industrial pulp and paper mill process water systems used in manufacturing food-contact pulp/paper and paperboard.

Review Outcome:

Based upon review of the submitted data for proposed registration of *BUSAN 1215* microbicide, AD/RASSB anticipates that the product will pose limited dermal/inhalation exposure concern for paper mill workers when handled and applied under conditions of use stipulated on the draft labeling and in Buckman's report (MRID 464581-01) detailing intended product use methods/worker activities, including exposure mitigation measures such as PPE and engineering controls, and industrial workplace monitoring of airborne ammonia.

The *BUSAN 1215* product formulation contains a low percentage of ammonia as a dilute aqueous solution (acute product toxicity category IV). The registrant stipulates handling of product by trained Buckman representatives only and mandatory use of dermal PPE. *(Note: PPE language should be added to product labeling precautionary statements.)* It is transported in sealed tote bins which are then attached to a closed, metering system. The product is pumped into the paper mill water system via a fixed piping and feed system (i.e., chemical feed skid). The mixing proportions for dosing the system are designed to consume a significant portion of the available ammonia. Overall, the product use conditions minimize any potential acute and chronic exposure risks for occupational handler/postapplication tasks.

As it pertains to worker exposure, this AD/RASSB review supports allowing the "new use" pattern for ammonia and identifies no obstacles for *BCMW/BUSAN 1215* product registration. We concur with Buckman's statements that: *"The low potential acute systemic toxicity, the restriction of*

the product to industrial use, protective closed-system application equipment and established regulatory guidelines for ammonia assure that this product can be safely used when handled according to label instructions."

Any future changes to the product use pattern and/or conditions of use will prompt AD/RASSB to reassess human exposure potential for *BUSAN 1215.*

Background:

The registrant held preliminary discussions with AD/RASSB in August and September of 2004 in preparation for submission of an acceptable registration application in January, 2005 for both a proposed manufacturing-use product (MUP) and industrial end-use product (EP) as *BCMW* and *BUSAN 1215* respectively. The EP, *BUSAN 1215* (EPA File Symbol 1448-UGG) is a direct repack of the formulator-use MUP, *BCMW* (EPA File Symbol 1448-UGE). Both products contain 7.59% aqueous ammonia (total ammonia) as a dilute ammonium solution formed from an [redacted][1] *BUSAN 1215* is applied in conjunction with a sodium hypochlorite source (12.5% a.i.) to form "monochloramine" in-situ, as the active component (microbicide) for treating pulp/paper mill water systems.[2, 3]

BUSAN 1215 was initially proposed for use in a variety of industrial cooling water system applications (e.g., cooling towers, recirculating cooling water systems, brewery/food pasteurizers, evaporative condensers, decorative fountains, and sewage/ wastewater systems) which have since been dropped from consideration by the registrant. Only the pulp/paper mill water system use patterns remain for exposure assessment. AD/RASSB will address separately (under DP Barcodes D313638 and D313639) any dietary concerns for potential ingestion of monochloramine residues leached from manufactured food-contact paper/paperboard.

To facilitate review, Buckman Laboratories, Inc. submitted draft labeling for *BCMW/ BUSAN 1215,* and data on product use (Series 875 GLN 875.1700 and 875.2700) and description of human activities (Series 875 GLN 875.2800) were provided in the Supplemental Report *"Mammalian Toxicology and Environmental Fate and Effects Data"* (MRID 464581-01) received January 31, 2005.

Overview of Product Use:

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[1] [redacted] are List 4B Inert Ingredients.

[2] Numerous sodium hypochlorite (12% a.i.) source products (e.g., *BUSAN 1125C*, EPA Reg. No. 1448-20001) are currently registered with the Agency for use as microbicides in treating industrial process water systems (including paper mills). Therefore, the use of sodium hypochlorite for water system chlorination is an established use pattern, not subject to reassessment in support of the proposed registration of *BUSAN 1215.*

[3] The monochloramine generation process is consistent with certain alternate disinfection techniques used for public drinking water systems where ammonia and hypochlorite react in water for "chloramination".

Inert ingredient information may be entitled to confidential treatment

The registrant-submitted documents indicate the following product use profile for the proposed *BUSAN 1215* industrial end-use product.

Table 1. *BUSAN 1215* Use Profile

Pulp and Paper Mill Process Water Systems (Microbicide)	***BUSAN 1215:*** This product is used for the control of algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products. [a]
Formulation	Liquid Concentrate (Supplied in semi-bulk shipment of sealed "transfer" tote bins.)
Active Ingredient % (PC Code)	***Ammonia (total)* (7.59%)** *(aqueous ammonia)* (005302) (A dilute ammonium solution formed from an [redacted]
Product Density	Bulk Density 9.59 lbs/gallon
Vapor Pressure	*Volatile* as 7510 mm Hg at 25 °C for aqueous ammonia.
Personal Protective Equipment (PPE)	***Per Labeling:*** Signal Word: CAUTION. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. ***Per Product Use Data:*** Trained Buckman representatives wear Dermal PPE for all handler tasks: protective eye-wear (goggles, face shield or safety glasses), impervious chemical-resistant gloves, and full body clothing (long sleeved shirt and long pants; socks and shoes) when handling. Inhalation PPE not specified since inhalation potential negated with use of engineering controls for closed metered delivery and established regulatory airborne exposure limit guidelines for ammonia. Although inhalation exposure is not anticipated due to use of engineered delivery systems (closed, metered feed) exposure values have been established for Ammonia which allow protective airborne monitoring for industrial workplace safety. **Exposure Values** a. IDLH: 300 ppm (NIOSH, 1997) b. TLV (8-hour TWA): 25 ppm (ACGIH, 1999) c. TLV STEL (15-minute TWA): 35 ppm (ACGIH, 1999) d. NIOSH REL (10-hour TWA): 25 ppm (18 mg/m3) e. NIOSH STEL (15-minute TWA): 35 ppm (27 mg/m3) f. OSHA PEL (8-hour TWA): 50 ppm (35 mg/m3) Legend : IDLH = Immediately dangerous to life and health ; NIOSH = National Institute of Occupational Safety and Health; TLV = Threshold limit value; TWA = Time-weighted average; STEL = Short-term

	exposure limit; ACGIH = American Conference of Governmental Industrial Hygienists; REL = Recommended exposure limit; OSHA = Occupational Safety and Health Administration; and PEL = Permissible exposure limit.
Use Application and Dosage Rates	***Per Labeling:*** *Use Application* **Pulp and Paper Mills:** This product is applied in conjunction with sodium hypochlorite (12.5%) to form monochloramine, a slower acting less aggressive oxidizing microbicide. The products are added to dilution water to achieve a minimum molar ratio of 1.5:1 of ammonia to oxidant, and this ratio is obtained by combining 0.6 fluid ounces of *BUSAN 1215* to 1 fluid ounce of sodium hypochlorite (12.5%). To ensure both handling safety and effectiveness, the monochloramine solution should be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited. Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained. The frequency of feeding and the duration of the treatment will depend on the severity of the problem.
Mix/Load/Application Method	***Per Product Use Data:*** **Application system (closed, metered equipment)** The product will be handled and applied only by trained Buckman representatives via engineering controls (Buckman semi-bulk transfer and chemical handling systems). Mixer/Loader: *BUSAN 1215* is packaged as semi-bulk "transfer" tote bins which connect directly to a base tote feed container via specialized fittings (discharge valve/discharge hose). A small vent cap located on top of the transfer tote is opened to prevent vapor lock allowing for closed gravity flow transfer (loading). Operators are not exposed directly to any material via inhalation during unloading due to the location of the small vent cap and where they are standing when they open the transfer valves (vent cap is above them). The loading process takes less than 10 minutes. All personnel are required to use proper PPE when handling. Application: After loading, the tote containing the chemical hooks directly to a feed skid with the use of Kam-Lok quick fit connectors and open/close valves. Further safety measures taken to keep personnel exposure to a minimum is the addition of a containment vessel so that if a leak should occur, or some circumstance requires the totes to be moved, the small quantity of chemical left in the connection hose can be drained to the containment vessel for disposal.

	Use of dedicated skid-mounted chemical dosing system ensures closed delivery of both aqueous ammonia (*Busan 1215*) and sodium hypochlorite (12 % a.i.) into water systems for closed in-situ generation of monochloramine solution. Feeding of the reactant product (monochloramine) is through a double-lined, hard-pipe into the application site. (See rough schematic in Appendix A.)

Source: Registrant submitted *BUSAN 1215* draft labeling of December 21, 2004 and related product use data (MRID 464581-01) received January 31, 2005.

[a] *BUSAN 1215* is proposed for use in maintaining the integrity of paper mill process water systems. In contrast to paper mill "preservative use patterns", *BUSAN 1215* is not intended to preserve papermaking substrates, such as: pulp/broke, paper coatings, slurries, emulsions or papermaking chemicals/inks.

Toxicological Considerations:

An overview of toxicological considerations are presented below based on a toxicology review memorandum, *"Hazard Assessment for Ammonia and Monochloroamine"* by Deborah Smegal, MPH, Toxicologist (DP Barcode D313637) dated December 9, 2005. Refer to this review for complete details on hazard characterization and data citations. Certain text are excerpted below.

The primary toxicity hazard identified for ammonia concentrates is acute dermal corrosivity and irritation to the respiratory system. Protecting occupational workers against dermal/eye injury and respiratory tract/mucosal damage from off-gassing of ammonia vapor (due to its high vapor pressure) is of particular concern for workplace safety.

There is no evidence that ammonia is a carcinogen. Nor does it appear to be mutagenic. Data are unavailable for assessing developmental/reproductive effects. Studies in the scientific literature indicate potential neurological effects in humans following inhalation/dermal exposure.

Acute Toxicity of Ammonia (Technical Source Chemicals and Industrial Concentrates)

Ammonia is a corrosive substance and the main toxic effects are restricted to the sites of direct contact (i.e., skin, eyes, respiratory tract, mouth, and digestive tract). It is an upper respiratory irritant in humans. The skin is extremely sensitive to both airborne ammonia and ammonia dissolved in water. Dermal exposures to liquid ammonia or concentrated solutions and/or ammonia gas are frequently occupationally related and produce cutaneous burns, blisters, and lesions of varying degrees of severity. The topical damage caused by ammonia is probably due mainly to its reactivity and irritation properties. Its high water solubility allows it to dissolve in moisture on these surfaces, react with fatty substances, be absorbed into deeper layers, and inflict extensive damage. The severity of the damage is proportional to the concentration and duration of exposure; flushing with water immediately after contact alleviates or prevents effects (ATSDR 2004). [Source: Agency for Toxic Substances and Disease Registry (ATSDR). September 2004. Toxicological Profile for Ammonia. U.S. Dept. of Health and Human Services.]

Acute Toxicity of BUSAN 1215

In aqueous solution, ammonia exists in equilibrium with ammonium hydroxide. Ammonia solutions can cause severe eye/dermal damage due to their caustic nature. However, as noted above, the effects are dependent on the concentration of ammonia in the solution and the duration of exposure. The proposed *BUSAN 1215* product contains a dilute ammonium concentration. Based on a review of registrant-submitted data for *BCMW/BUSAN 1215*, the following low acute toxicity potential (Toxicity Category IV) was shown for the product formulation:

Table 2. Acute Product Toxicity Data on Busan 1215

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity	464351-08	$LD_{50} > 5000$ mg/kg	IV
870.1200 Acute dermal toxicity	464351-09	$LD_{50} > 5000$ mg/kg	IV
870.1300 Acute inhalation toxicity	464351-10	LC50 $\geq$ 2.08 mg/L (4-hr)	IV
870.2400 Acute eye irritation	464351-11	Minimally irritating (rabbit) Irritation cleared within 48 hours	IV
870.2500 Acute dermal irritation	464351-12	Slightly irritating	IV
870.2600 Skin sensitization	464351-13	Not a skin sensitizer (guinea pig)	NA

Source: *March 16, 2005 Review Memoranda, I. Blackwell, Biologist, AD/PSB, DP Barcodes D313223 and D313227.*

Inhalation Toxicity Endpoint Selection

Epidemiological Study Selected: Holness, D.L. et al. (1989) *Acute and chronic respiratory effects of occupational exposure to ammonia.* Am. Ind. Hyg. Assoc. J. 50(12):646-650.

Executive Summary: Holness et al. (1989) investigated production workers exposed to ammonia in a soda ash facility. All of the available 64 production workers were invited to participate and 82% agreed to be evaluated. The control group consisted of 31 other plant workers from stores and office areas of the plant without previous exposure to ammonia. The mean age of the workers was 38.9 years and duration of exposure was 12.2 years. Weight was the only statistically significant difference in demographics found after comparing height, weight, years worked, % smokers and pack-years smoked. The mean TWA ammonia exposures based on personal sampling over one work shift (average sample collection 8.4 hours) of the exposed and control groups were 9.2 ppm (6.4 mg/cu.m) and 0.3 ppm (0.21 mg/cu.m), respectively.

A questionnaire was administered to obtain information on exposure and work histories and to determine eye, skin and respiratory symptomatology (based on the American Thoracic Society [ATS] questionnaire [Ferris, 1978]). Spirometry (FVC, FEV-1, FEF50 and FEF75) was performed according to ATS criteria at the beginning and end of each work shift on the first workday of the week (day 1) and the last workday of the week (day 2). Differences in reported symptoms and lung function between groups were evaluated using the actual values and with age, height and pack-years smoked as covariates in linear regression analysis. Baseline lung function results were expressed as percent of predicted values calculated from Crapo et al. (1981) for FVC and FEV-1 and from Lapp and Hyatt (1967) for FEF50 and FEF75.

No statistical difference in the prevalence of the reporting of symptoms was evident between the exposed and control groups, although workers reported that exposure at the plant had aggravated specific symptoms including coughing, wheezing, nasal complaints, eye irritation, throat discomfort and skin problems. Based on the lack of subjective symptomatology and changes in spirometry, this study establishes a free-standing TWA NOAEL of 9.2 ppm (6.4 mg/cu.m). Adjustment for the TWA occupational scenario results in a NOAEL(HEC) of 2.3 mg/cu.m.

Table 3. Summary of Toxicological Dose and Endpoints for Ammonia [1]

Occupational Exposure Scenario	Dose Used in Risk Assessment	Target Margin of Exposure (MOE) for Occupational Exposure	Study and Toxicological Effects
Dermal (all durations)	A dermal endpoint was not selected. Labels will specify the use of gloves, full body clothing and eye protection. Closed delivery systems negate dermal contact with chemical during Mixing/Loading/Application.		
Inhalation (all durations)	8-hr TWA NOAEL= 6.4 mg/m^3 (9.2 ppm) 24-hr adjusted NOAEL (HEC) = 2.3 mg/m^3 (3.3 ppm) (Continuous Occupational Exposure) [a] Inhalation RfC = 0.1 mg/m^3 (Lifetime Daily Exposure for General Population) [b]	LOC for MOE = 30 [c] Based on UF = 10X (intra-species extrapolation) and 3X (database deficiencies)	Occupational Study (Holness et al. 1989) LOAEL= none Lack of evidence of decreased pulmonary function or changes in subjective syptomatology. See IRIS record (USEPA 2005a) for more detailed discussion. [2]

Source: Review Memorandum, "Hazard Assessment for Ammonia and Monochloroamine" by D. Smegal, MPH, Toxicologist (DP Barcode D313637) dated December 9, 2005.

[1] TWA = time-weighted average, UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, LOC= level of concern , MOE = margin of exposure, HEC= human equivalent concentration, RfC = reference concentration.

[2] *U.S. EPA 2005a. Integrated Risk Information System for Ammonia.* http://www.epa.gov/iris/subst/0422.htm.

[a] The NOAEL of 6.4 mg/m^3 (9.2 ppm) from an occupational study is based on an 8-hour TWA and was selected based on lack of evidence of decreased pulmonary function or changes in subjective syptomatology in the occupational study (Holness et al. 1989). This NOAEL is adjusted to account for continuous occupational exposure as a human equivalent concentration (HEC) of 2.3 mg/m^3 according to the following equation:

NOAEL (HEC) = 6.4 mg/m^3 × (MVho/MVh) × 5 days/7 days

Where: MVho is the breathing volume for an 8-hour occupational exposure (10 m^3); and MVh is the breathing volume for a 24-hour continuous exposure (20 m^3).

A NOAEL (HEC) of 2.3 mg/m^3 is extrapolated to 3.3 ppm:
(where 1 ppm = 0.707mg/m^3, so 2.3 mg/m^3 ÷ 0.707mg/m^3 = 3.3 ppm).

[b] The 24-hour adjusted NOAEL of 2.3 mg/m^3 is the basis of the Agency's inhalation reference concentration (RfC) presented on the Integrated Risk Information System (IRIS) and represents Agency consensus. Since ammonia is a respiratory irritant, the Agency believes that the irritation potential would limit exposure. The RfC represents an estimate of a daily inhalation exposure of the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime.

An inhalation RfC of 0.1 mg/m^3 is established as follows: RfC = NOAEL (HEC) ÷ UF

Where: NOAEL (HEC) = 2.3 mg/m^3 and UF = 30 (2.3/30 = 0.0766 rounded up to 0.1)

[c] An inhalation MOE of 30 is adequate for all durations. An uncertainty factor of 10 is used to allow for the protection of sensitive individuals (intra-species extrapolation). Because it is based on a human epidemiological study, no inter-species safety factor is required. A factor of 3 was used to account for several database deficiencies including the lack of chronic data, and the lack of reproductive and developmental toxicology studies.

cc: Doreen Aviado/RASSB/AD
Chemical/Circulation Files

APPENDIX A:

Description and Schematic of *BUSAN 1215* Chemical Feed Skid

Buckman Laboratories, Inc. submitted data on product use (Series 875 GLN 875.1700 and 875.2700) and description of human activities (Series 875 GLN 875.2800) for *BCMW/BUSAN 1215* as provided in the Supplemental Report *"Mammalian Toxicology and Environmental Fate and Effects Data"* (MRID 464581-01) received January 31, 2005. An excerpt on the dedicated *BUSAN 1215* feed equipment follows:

"BUSAN 1215 is an [redacted]. The product is designed to be mixed with sodium hypochlorite (12% a.i. source) added through a carefully designed chemical feed skid that allows the two to mix and form monochloramine. The chemical feed skid is designed to allow the introduction of *BUSAN 1215* to a pipe where there is continuous flow through dilution water available. The additional dilution of the product is insured by sending the product and dilution water through an in-line mixer so that the hypochlorite and ammonia mixture will react to form monochloramine before being sent to its intended treatment location.

The chemical feed system has been designed to incorporate numerous safety features that include:

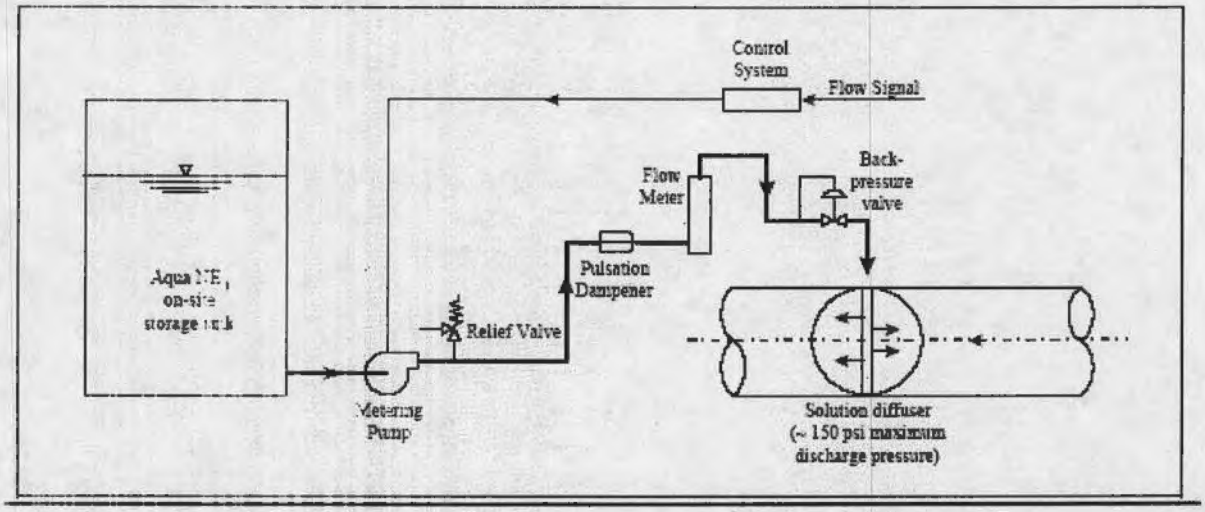
- Double walled chemical dosing lines;
- Position and size of installation connections to mother/daughter chemical tanks make it impossible to mix the chemicals external to the unit;
- Degassing lines on the outside of the unit to prevent bleach from decomposing and gassing;
- Safety shower on unit;
- Lock on unit door to prevent unauthorized entry;
- Removal of door panels on front/back to give access to all internal pumps, valves, etc..;
- Removable spill containers under all connection locks;
- Multiple shut off alarms and switches are included to prevent any unsafe condition.

For example, the following will put the unit in alarm mode:

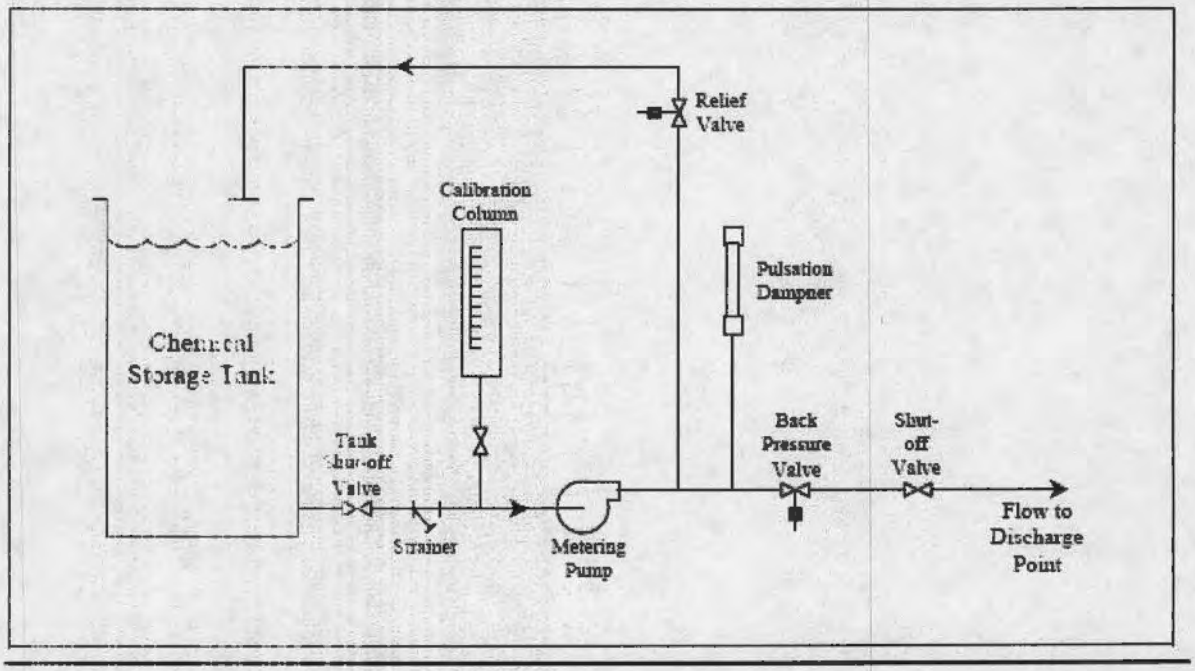
external or internal power failure,
internal leak detection sensor activated,
insufficient dilution water flow sensor,
external manual emergency shut off switch,
low chemical detection sensors.

When an alarm condition is evident, the unit stops feeding chemicals and automatically flushes all chemical feed lines with fresh water so that no storage hazards will exist. The valves that control the fresh water flush are pneumatically operated by an attached pressurized air tank so that the unit will be able to shut down safely should a power outage occur."

Generic Chemical Feed System Schematic for Water Treatment



Aqueous Ammonia Feed System



Hypochlorite Feed System

Source "Alternative Disinfectants and Oxidants Guidance Manual." US EPA, Office of Water, EPA 815-R-99-014. April 1999.

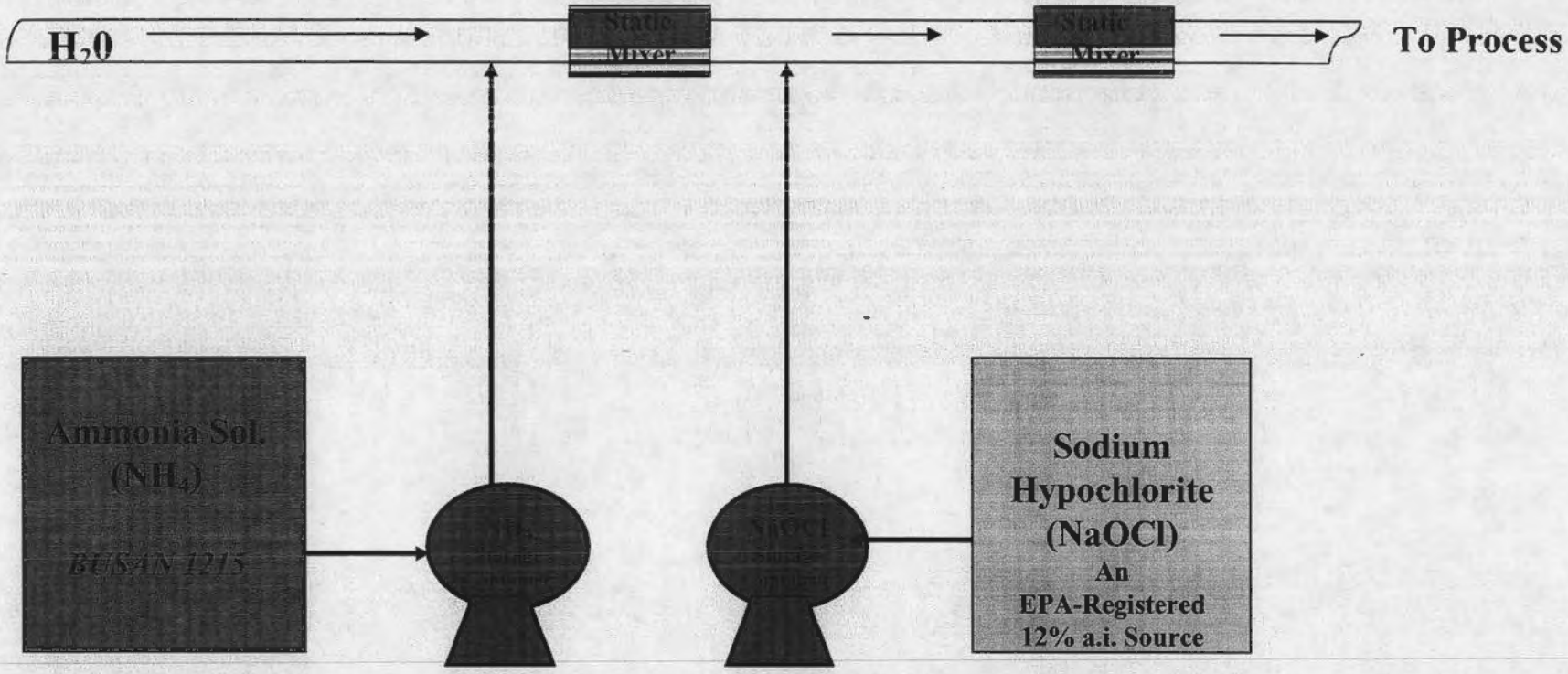


Diagram of Closed Delivery via Skid-Mounted Chemical Feed Dosing

Source: Buckman Laboratories, Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA Office of Pesticide Programs

January 30, 2008

MEMORANDUM

SUBJECT: **Environmental Exposure Assessment for Releases of BUSAN 1215 from Sewage and Wastewater Systems**

From: **Siroos Mostaghimi, Senior Scientist** Siroos - Mostaghimi
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

To: **Velma Noble, PM 31**
Regulatory Management Branch I
Antimicrobials Division (7510P)

Thru: **Norm Cook, Chief** N P Cook
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

DP Barcode: 34 2578

Pesticide Chemical No.: 005302

Attached please find the modeling report for the environmental exposure assessment of the releases of BUSAN 1215 from sewage and wastewater systems.

Introduction

This report presents an environmental exposure assessment for releases of BUSAN 1215 used for control of algae, bacteria, and fungi in sewage and wastewater systems. For this analysis, the Probabilistic Distribution Model (version 4) was used to estimate the number and percentage of days per year with concentrations of the BUSAN 1215 biocidal compound monochloramine exceeding ecotoxicity benchmarks of concern. The analysis was performed using the maximum BUSAN 1215 application rate as determined from the proposed amended product label. The approach used for this assessment is based on the methodology previously developed for the environmental exposure assessment for BUSAN 1215 releases from once-through cooling water systems (EPA, 2008 a) and sea water desalination and reverse osmosis systems (EPA, 2008 b).

According to the proposed amended product label, the active ingredient in BUSAN 1215 is ammonia. However, BUSAN 1215 is used in conjunction with sodium hypochlorite (i.e., bleach), which reacts with ammonia to form a family of microbicidal compounds called chloramines. Because chloramines are the actual biocidal agents of BUSAN 1215 use, the environmental exposure assessment is performed for chloramines instead of ammonia.

1. Methodology

Components of the methodology used to assess environmental exposures to monochloramine include the probabalistic distribution model (PDM), effluent discharge volumes, receiving surface water flows, monochloramine concentrations in effluent, and monochloramine concentrations of concern (COCs) for environmental exposures.

1.1 PDM Model

PDM is a screening-level exposure assessment tool developed by EPA to model chemical releases from point sources to flowing surface waters. The PDM component within EPA's Exposure and Fate Assessment Screening Tool Version 2.0 (E-FAST2) was used for this assessment.[1]

PDM uses detailed U.S. Geological Survey (USGS) stream flow data and facility-specific data from National Pollutant Discharge Elimination System (NPDES) permits to model chemical releases from actual facilities. For a modeling period of a given number of days, PDM calculates probability distribution of the chemical concentration in the receiving stream, and then estimates the number of days during which the in-stream chemical concentration is expected to exceed a COC. PDM counts a day as having an exceedence of a COC if the COC is exceeded for any part of a 24-hour day. As a

[1] The E-FAST2 model is available from EPA at http://www.epa.gov/opptintr/exposure/pubs/efastdl.htm and documentation is available at http://www.epa.gov/opptintr/exposure/pubs/efast2man.pdf.

screening-level model, PDM outputs do not include the duration, location, or aerial extent of exceedences.

Inputs to PDM include facility NPDES number, pretreatment release (i.e., loading rate), post-treatment release, number of release days, and COCs. PDM contains facility-specific data on wastewater discharges and receiving surface waters. These data were used to develop modeling scenarios as described in Sections 1.2, 1.3, and 1.5.

1.2 Effluent Discharge Volumes

The proposed use of BUSAN 1215 in "sewage and wastewater systems" may apply to processes that handle sewage or any other type of industrial wastewater. Therefore, this use category may encompass a wide variety wastewater systems and waste stream characteristics. Because sewage systems are specifically identified as a component of this use category, data for surface water discharges from publicly owned treatment works (POTWs) were used to develop effluent and receiving surface waters assumptions for the analysis. The specific use of BUSAN 1215 in sewage systems has not been identified. However, is not expected to be used as an antifoulant in operating sewage treatment systems.

PDM contains NPDES effluent discharge data for 9,623 facilities identified as POTWs by standard industrial classification (SIC) code 4952 (sewerage systems). These data were used to identify percentiles of POTW effluent discharge volumes. 635 facilities were excluded from the percentiles analysis because their reported discharges were zero. Table 1 identifies selected effluent discharge percentiles calculated based on the remaining 8,988 POTWs.

Table 1
Percentiles of POTW Effluent Discharges

Percentile	Effluent Discharge (MLD)
100^{th} (maximum)	31,794
99^{th}	128
95^{th}	26.5
90^{th}	11.5
75^{th}	3.49
50^{th}	0.95

MDL= Million Liters per Day

1.3 Receiving Surface Water Flows

The flows of surface water bodies that receive effluent discharges from POTWs were characterized using USGS stream flow data obtained from PDM. The mean stream flows were identified for each of the 8,988 POTWs that were used to characterize effluent discharges. Selected stream flow percentiles are presented in Table 2.

Table 2
Percentiles of Receiving Surface Water Flows

Percentile	Mean Annual Stream Flow (MLD)
100^{th} (maximum)	1,544,640
99^{th}	291,444
95^{th}	48,084
90^{th}	15,400
75^{th}	2,356
50^{th}	543

1.4 Monochloramine Concentrations in Effluent

BUSAN 1215 is used in conjunction with sodium hypochlorite (i.e., bleach) to form a family of microbicidal compounds called chloramines. Chloramines are formed when ammonia from the BUSAN 1215 reacts with chlorine from the sodium hypochlorite to produce a mixture of monochloramine (NH_2Cl), dichloramine ($NHCl_2$), or nitrogen trichloride (NCl_3). The relative proportions of these chloramines are determined by the pH of the solution. A detailed discussion of monochloramine chemistry may be found in the environmental exposure assessment of BUSAN 1215 releases from once-through cooling water systems (EPA, 2008a). That discussion shows that essentially all of the chloramine formed by the use of BUSAN 1215 according to label instructions will be monochloramine.

Chlorine-based disinfectants, including monochloramine, are typically applied at rates adjusted to oxidative "chlorine demand" of the water to be treated. Application is controlled by monitoring the post-disinfection residual chlorine concentration and not by meeting a prescribed pre-disinfection dose concentration. According to label instructions, which are summarized in Table 3, BUSAN 1215 is to be applied to attain a residual total chlorine concentration of no more than 5 ppm in excess of system oxidant demand. This concentration was used as the assumed effluent monochloramine concentration for the environmental exposure assessment.

Table 3
BUSAN 1215 Dosage Information for Industrial Water Systems

Product	Percent Active Ingredient	Label Directions	Application Rate for Analysis
BUSAN 1215	Ammonia 7.59%	When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve total chlorine residual of at least 1 ppm in excess of the system oxidant demand ... mix 0.5 fluid ounces BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt).	*Continuous Treatment:* Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. *Intermittent Treatment:* Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours.

Foulant control may be achieved by either an intermittent or a continuous application of BUSAN 1215 and sodium hypochlorite solution. Both methods are intended to achieve the maximum concentration 5 ppm total chlorine in the treated water, and the maximum intermittent application (i.e., 60 minutes every hour) is equivalent to continuous application. Therefore, the maximum continuous application rate was chosen as the application scenario for this analysis.

Total residual chlorine is expected to consist primarily of HOCl, OCl-, and monochloramine, with monochloramine predominating (ICF, 2007a). For a conservative, screening-level analysis, it is reasonable to assume that 100 percent of the 5 ppm residual chlorine is present as monochloramine. This assumption is likely to overestimate the actual percentage of monochloramine and, therefore, the concentration of monochloramine. However, the concentration may be underestimated due to the assumption that total residual chlorine does not exceed 5 ppm.

According to the proposed label, sodium metabisulfite may be added to systems treated with BUSAN 1215 to neutralize residual monochloramine. Because neutralization may or may not be performed and may or may not be completely effective at neutralizing monochloramine, the post-neutralization concentration of monochloramine may range from 0 to 100 percent (i.e., 0 ppm to 5 ppm) of the assumed pre-neutralization

concentration. For this screening level assessment, it was conservatively assumed that sodium metabisulfite neutralization is not used and that the effluent contains the maximum monochloramine concentration that may be expected from label instructions.

1.5 Monochloramine Release Scenarios

Twelve monochloramine release scenarios were developed by combining assumptions about the effluent discharge rate and receiving stream flow. For this screening-level analysis, all 12 scenarios were included the maximum residual monochloramine concentration of 5 ppm. Table 4 identifies the 12 scenarios.

Table 4
Modeling Scenarios for Environmental Exposure Assessment for Monochloramine Releases from Sewage and Wastewater Systems

Scenario	Stream Flow Percentile	Mean Stream Flow (MLD)	Plant Flow Percentile	Effluent Discharge (MLD)	Monochloramine Concentration in Effluent (PPM)
1	50	543	50	0.95	5
2	50	543	90	11.5	5
3	50	543	95	26.5	5
4	50	543	99	128	5
5	90	15,400	50	0.95	5
6	90	15,400	90	11.5	5
7	90	15,400	95	26.5	5
8	90	15,400	99	128	5
9	95	48,084	50	0.95	5
10	95	48,084	90	11.5	5
11	95	48,084	95	26.5	5
12	95	48,084	99	128	5

250 release days were assumed for all scenarios. This approach assumes that BUSAN 1215 is not applied on weekends and holidays.

1.6 Monochloramine COCs

Table 5 identifies the seven COCs selected for this analysis. These COCs were obtained from references identified by searching the TOXNET online database.[2] The COCs were selected to include freshwater and marine species and a broad representation of aquatic biota and reported sensitivities. All COCs are from peer-reviewed sources.

[2] The TOXNET database may be accessed at: http://toxnet.nlm.nih.gov/

2. Estimated Exceedences of Monochloramine COCs in Receiving Surface Waters

Tables 6 through 8 present the predicted numbers and percentages of days with downstream concentrations of monochloramine above COCs. Table 6 presents results for Scenarios 1 through 4 (i.e., the scenarios based on median steam flow), Table 7 presents results for Scenarios 5 through 8 (i.e., the scenarios based on 90th percentile stream flow), and Table 8 presents results for Scenarios 9 through 12 (i.e., the scenarios based on 95th percentile stream flow). The percentages of release days with exceedences also are shown in Figures 1 through 3.

Table 5
Concentrations of Concern Selected for the Environmental Exposure Assessment of Monochloramine

COC	Test Species	Endpoint Type	Species Habitat	Reference
12 µg/L	*Ceriodaphnia dubia* (Water flea)	LC50	Freshwater	Taylor (1993)
350 µg/L	*Notropis atherinoides* (Emerald shiner)	LC50	Freshwater	Brooks and Seegert (1978)
560 µg/L	*Homarus americanus* (American lobster, stage 1 larvae)	LC50	Marine	Capuzzo et al. (1976)
570 µg/L	*Cynoscion nebulosus* (Spotted seatrout, 10 hr old eggs)	LC50	Estuarine/Marine	Johnson et al. (1977)
650 µg/L	*Ictalurus punctatus* (Channel catfish)	LC50	Freshwater	Brooks and Seegert (1978)
1,230 µg/L	*Lepomis macrochirus* (Bluegill sunfish)	LC50	Freshwater	Brooks and Seegert (1978)
2,030 µg/L	*Gambusia affinis* (Western mosquitofish)	LC50	Freshwater (euryhaline)	Cherry et al. (1982)

When the 90th percentile stream flow was assumed (refer to Table 7 and Figure 2) only the lowest COC was exceeded on a majority of release days (with Scenarios 6 through 8). The remaining COCs (i.e., 350 µg/L and above) were exceeded on seven percent or less of the release days when effluent discharge rates equaled the 95th percentile or less. When the 99th percentile effluent discharge rate was assumed (i.e., Scenario 8), the percentage of release days with exceedences dropped from 90 percent for the lowest COC to 36 percent of less for the higher COCs.

Scenario 1 includes the median effluent discharge rate and the median stream flow. With this scenario, the lowest COC was exceeded on 92 percent of the release days), while higher COCs were exceeded on no more than 12 percent of the release days. When higher percentile effluent discharge assumptions were paired with the median stream flow assumption (i.e., Scenarios 2 through 4), the majority of the COCs were exceeded on at least half of the release days.

3. Limitations and Uncertainties

This analysis is a screening level evaluation of the potential for discharges from sewage and wastewater systems to exceed ecotoxicity COCs for monochloramine, which is formed during the use of BUSAN 1215. The methodology involves the following potential limitations:

- The BUSAN 1215 use category "sewage and wastewater systems" encompasses a broad range of potential industries and waste stream characteristics. The scenarios evaluated in environmental exposure assessment were based on effluent discharge volume and receiving stream flow data for POTWs, which may not be representative of other types of industries to which this use category may apply.

- Monochloramine concentrations in effluent are affected by the pH, temperature, and water chemistry of the water in the treated system. All ammonia, chlorine, and monochloramine are assumed to originate with the addition of BUSAN 1215 and sodium hypochlorite. That is, it is assumed that there are no background concentrations of these chemicals in the pre-treatment effluent stream of the receiving surface waters.

Table 6
Estimated Number and Percentage of Days with Downstream Exceedences of Monochloramine COCs – Scenarios 1 to 4

COC (µg/L)	Number of Days Above COC				Percent of 250 Release Days Above COCS				Percent of 365 Days/Year Above COCS			
	Scen. 1	Scen. 2	Scen. 3	Scen. 4	Scen. 1	Scen. 2	Scen. 3	Scen. 4	Scen. 1	Scen. 2	Scen. 3	Scen. 4
12	230	250	250	250	92%	100%	100%	100%	63%	68%	68%	68%
350	30	188	228	248	12%	75%	91%	99%	8%	52%	62%	68%
560	15	145	210	248	6%	58%	84%	99%	4%	40%	58%	68%
570	13	145	210	248	5%	58%	84%	99%	4%	40%	58%	68%
650	13	135	203	245	5%	54%	81%	98%	4%	37%	56%	67%
1,230	0	80	150	238	0%	32%	60%	95%	0%	22%	41%	65%
2,030	0	55	108	220	0%	22%	43%	88%	0%	15%	30%	60%

Table 7
Estimated Number and Percentage of Days with Downstream Exceedences of Monochloramine COCs – Scenarios 5 to 8

COC (µg/L)	Number of Days Above COC				Percent of 250 Release Days Above COCS				Percent of 365 Days/Year Above COCs			
	Scen. 5	Scen. 6	Scen. 7	Scen. 8	Scen. 5	Scen. 6	Scen. 7	Scen. 8	Scen. 5	Scen. 6	Scen. 7	Scen. 8
12	18	160	209	247	7%	64%	84%	99%	5%	44%	57%	68%
350	0	4	17	91	0%	2%	7%	36%	0%	1%	5%	25%
560	0	2	8	61	0%	1%	3%	24%	0%	1%	2%	17%
570	0	2	8	60	0%	1%	3%	24%	0%	1%	2%	16%
650	0	1	6	53	0%	<1%	2%	21%	0%	<1%	2%	15%
1,230	0	0	2	25	0%	0%	1%	10%	0%	0%	1%	7%
2,030	0	0	1	13	0%	0%	<1%	5%	0%	0%	<1%	4%

Table 8
Estimated Number and Percentage of Days with Downstream Exceedences of Monochloramine COCs – Scenarios 9 to 12

COC (µg/L)	Number of Days Above COC				Percent of 250 Release Days Above COCS				Percent of 365 Days/Year Above COCs			
	Scen. 9	Scen. 10	Scen. 11	Scen. 12	Scen. 9	Scen. 10	Scen. 11	Scen. 12	Scen. 9	Scen. 10	Scen. 11	Scen. 12
12	1	63	126	226	<1%	25%	50%	90%	<1%	17%	35%	62%
350	0	0	1	18	0%	0%	<1%	7%	0%	0%	<1%	5%
560	0	0	0	8	0%	0%	0%	3%	0%	0%	0%	2%
570	0	0	0	8	0%	0%	0%	3%	0%	0%	0%	2%
650	0	0	0	6	0%	0%	0%	2%	0%	0%	0%	2%
1,230	0	0	0	2	0%	0%	0%	1%	0%	0%	0%	1%
2,030	0	0	0	0	0%	0%	0%	0%	0%	0%	0%	0%

Figure 1
Average Percent of Release Days with Downstream Monochloramine Concentrations above COCs – Scenarios 1 to 4

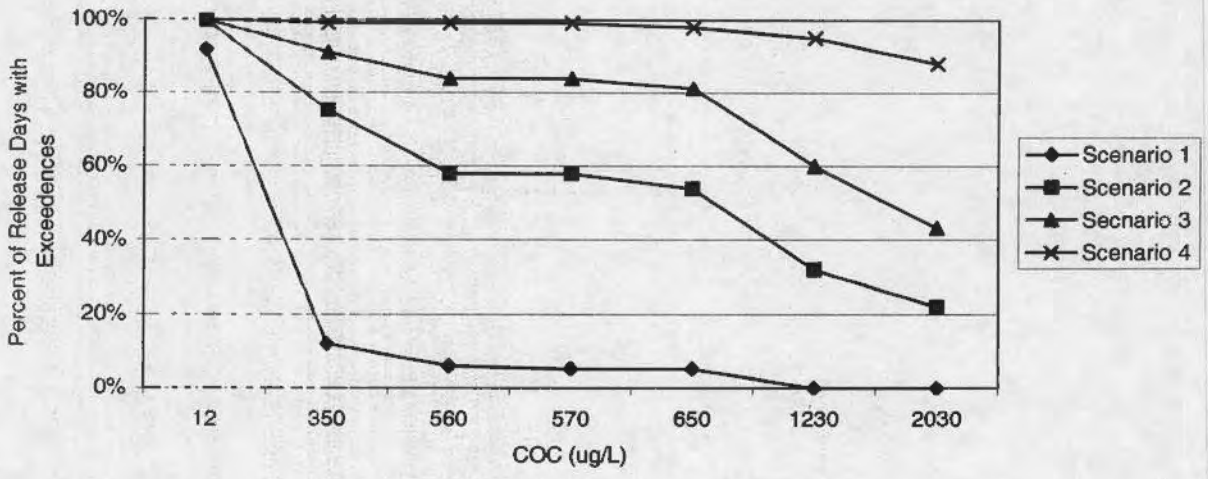


Figure 2
Average Percent of Release Days with Downstream Monochloramine Concentrations above COCs – Scenarios 5 to 8

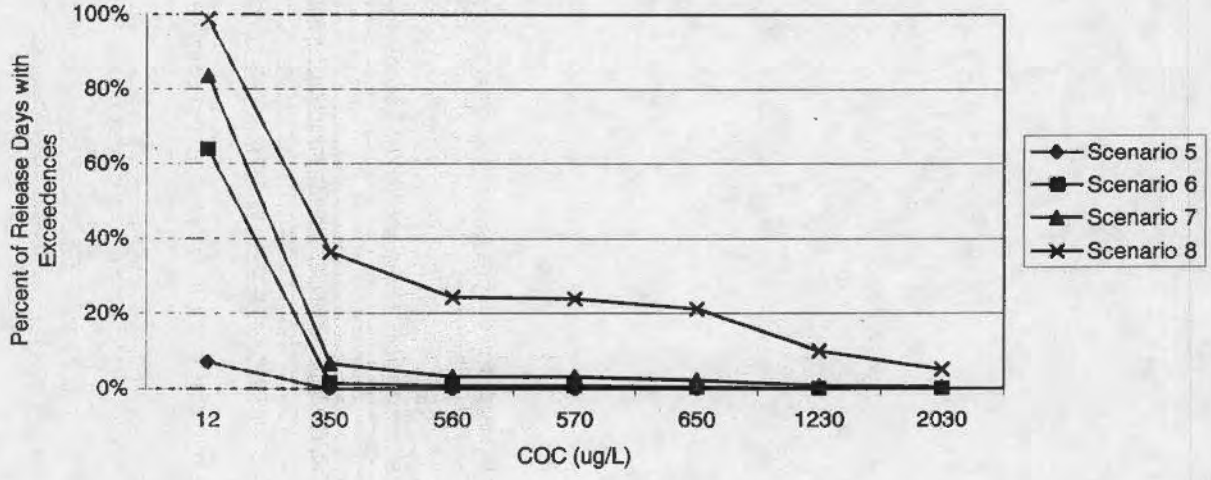


Figure 3
Average Percent of Release Days with Downstream Monochloramine Concentrations above COCs – Scenarios 9 to 12

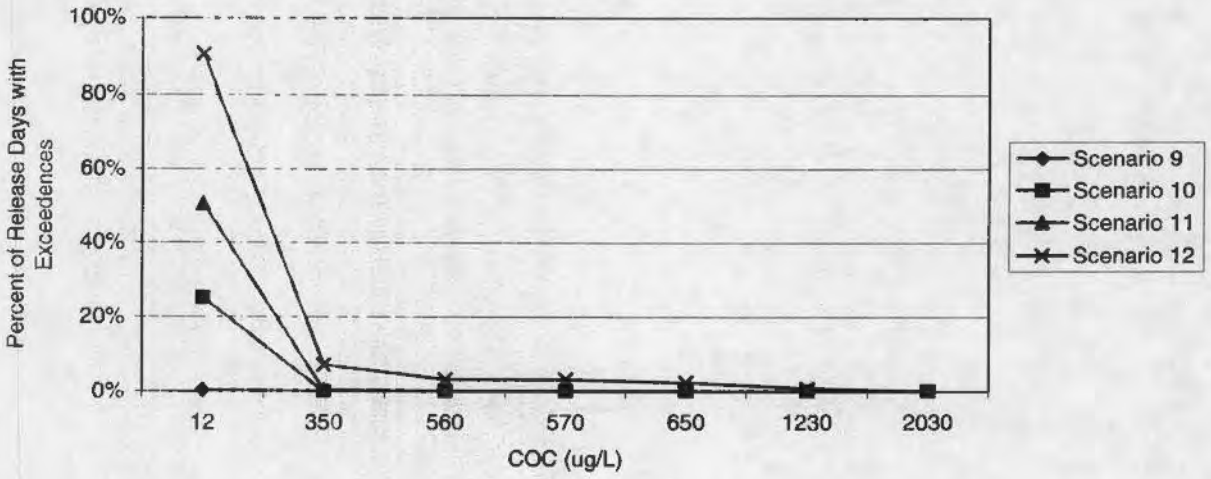
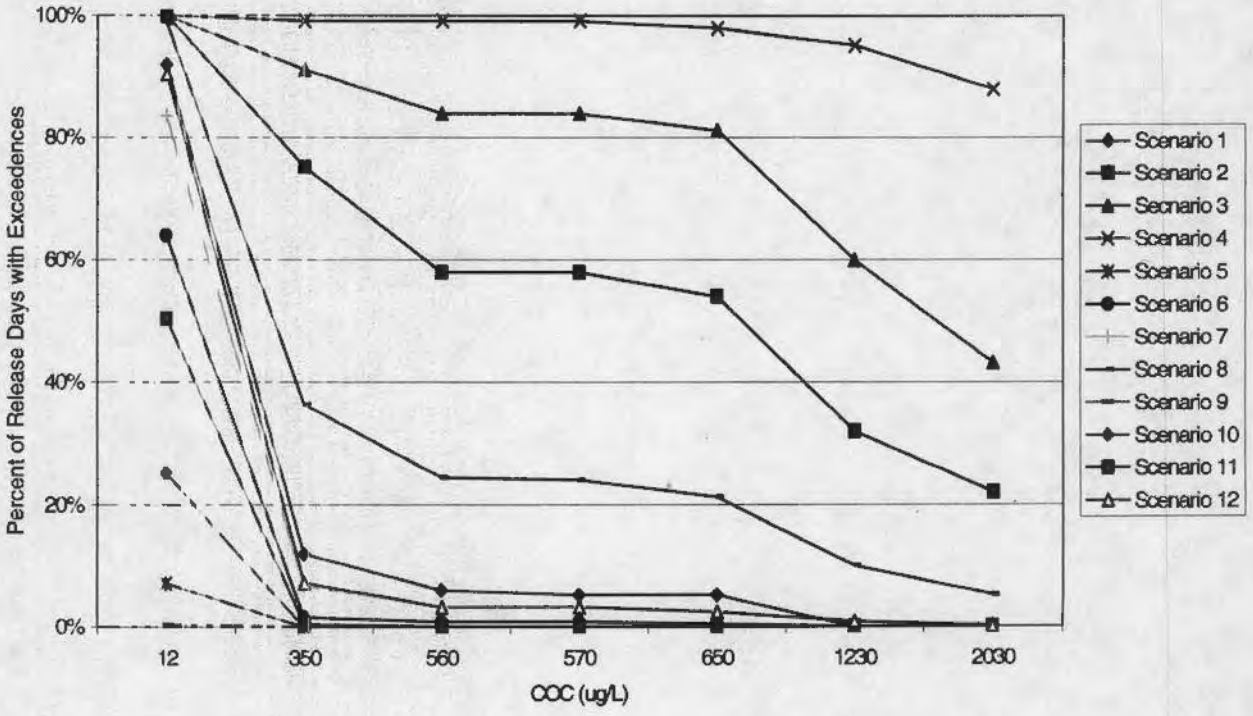


Figure 4
Average Percent of Release Days with Downstream Monochloramine Concentrations above COCs for all Scenarios

- Total residual chlorine is expected to consist primarily of HOCl, OCl-, and monochloramine, with monochloramine predominating (ICF, 2007a). This analysis



- assumes that 100 percent of the total residual chlorine in the effluent is monochloramine. Further, all modeled scenarios use the maximum expected residual monochloramine concentration in effluent (i.e., 5 ppm). For example, the methodology assumes that sodium metabisulfite or other chemicals are not used to neutralize residual monochloramine in the wastewater prior to disposal. These conservative assumptions are likely to result in overestimates of the numbers of days with downstream concentrations of monochloramine above COCs.

- It is assumed that monochloramine does not react (e.g., with suspended organic matter in the receiving water body) between the point of discharge and the point of ecological exposure.

- Because COC exceedences predicted by the PDM do not necessarily occur on consecutive days, the analysis may overestimate the actual potential for ecological toxicity impacts. The numbers of days with exceedences of COCs have not been compared to the numbers of days of exposure used in the studies from which the COCs were obtained.

- Downstream concentrations of monochloramine are considered to exceed a COC on any given day if the COC is exceeded for any portion of the day. PDM does not identify the duration of the exceedences, and the daily scale results may overestimate the actual potential for monocbloramine releases to result in ecological risks.

- The analysis used an assumed release period of 250 days. This assumption is likely to overestimate the number of release days for BUSAN 1215 treatment, especially for initial control. Thus, the results of the analysis may overestimate the number of days with downstream monochloramine concentrations above COCs.

- The release scenarios were based on the maximum application rate based on product labels. It may be possible to control of target organisms with application rates below the maximum. In addition, continuous dosing was assumed throughout the release period. This assumption may overestimate the daily treatment duration that would be required for effective control.

- For this analysis, effluent discharge rates were assumed to equal the lower of either facility-specific effluent flow rates or the 7Q10 flows of the receiving streams. This approacb may over or underestimate average actual effluent discharges.

3. References

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Siroos Mostaghimi, RASSB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA Office of Pesticide Programs

January 28, 2008

MEMORANDUM

SUBJECT: **Environmental Exposure Assessment for Releases of BUSAN 1215 from Seawater Desalinization and Reverse Osmosis Systems**

From: **Siroos Mostaghimi, Senior Scientist** Siroos Mostaghimi
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To: **Velma Noble, PM 31**
Regulatory Management Branch I
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Thru: **Norm Cook, Chief**
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

DP Barcode: 34 2578

Pesticide Chemical No.: 005302

Attached please find the modeling report for the environmental exposure assessment of the BUSAN 1215 from Seawater desalinization and reverse osmosis systems.

Introduction

This report presents an environmental exposure assessment for releases of BUSAN 1215 used for control of algae, bacteria, and fungi in seawater desalination and reverse osmosis systems. For this analysis, the Probabilistic Distribution Model (version 4) was used to estimate the number and percentage of days per year with concentrations of the BUSAN 1215 biocidal compound monochloramine exceeding ecotoxicity benchmarks of concern. The analysis was performed using the maximum BUSAN 1215 application rate as determined from the proposed amended product label. The approach used for this assessment is based on the methodology previously developed for the environmental exposure assessment for BUSAN 1215 releases from once-through cooling water systems (EPA, 2008).

According to the proposed amended product label, the active ingredient in BUSAN 1215 is ammonia. However, BUSAN 1215 is used in conjunction with sodium hypochlorite (i.e., bleach), which reacts with ammonia to form a family of microbicidal compounds called chloramines. Because chloramines are the actual biocidal agents of BUSAN 1215 use, the environmental exposure assessment is performed for chloramines instead of ammonia.

1. Seawater Desalination and Reverse Osmosis

Reverse osmosis is one of several methods used to purify water. In a reverse osmosis systems, physical pressure in excess of osmotic pressure is applied to influent water to force water through a semi-permeable membrane. When used for water purification, the membrane is designed to selectively pass water while preventing the passage of salt ions and most other solutes. A reverse osmosis system produces two effluent streams, a purified water stream, and a concentrated wastewater stream.

Reverse osmosis is increasingly used where available water supplies (e.g., sea water, ground water) must be desalinated, softened, or decontaminated to serve as drinking water sources (AMTA, 2007a). In some cases, reverse osmosis is applied to municipal or industrial wastewater streams to reduce the volumes for disposal or to "reclaim" a portion for irrigation, industrial processes, or other uses (AMTA, 2007b).

The purified water stream is likely to be of a higher quality than necessary to meet safe drinking water standards. In some cases the purified water is blended with influent water for an increased production of drinking water of acceptable quality (Hatch Mott MacDonald, 2007).

Concentrated wastewaters from reverse osmosis processes are disposed of one of six methods, including surface water discharge, sewer discharge, deep groundwater well injection, irrigation, evaporation ponds, or thermal reduction processes (AMTA, 2007c). Discharges of concentrated wastewater to surface water are subject to regulation under the National Pollution Discharge Elimination System (NPDES) permitting under the Clean

Water Act. This may explain why deep well injection is a very common disposal choice for reverse osmosis drinking water facilities at inland locations (AMTA, , 2007c), and surface water discharge is generally associated with the ocean other tidal or brackish waters (AMTA, 2007c; Hatch Mott MacDonald, 2007).

2. Methodology

Components of the methodology used to assess environmental exposures to monochloramine include the probabalistic distribution model (PDM), effluent discharge volumes, receiving surface water flows, monochloramine concentrations in effluent, and monochloramine concentrations of concern (COCs) for environmental exposures.

2.1 PDM Model

PDM is a screening-level exposure assessment tool developed by EPA to model chemical releases from point sources to flowing surface waters. The PDM component within EPA's Exposure and Fate Assessment Screening Tool Version 2.0 (E-FAST2) was used for this assessment.[1]

PDM uses detailed U.S. Geological Survey (USGS) stream flow data and facility-specific data from National Pollutant Discharge Elimination System (NPDES) permits to model chemical releases from actual facilities. For a modeling period of a given number of days, PDM calculates prohability distribution of the chemical concentration in the receiving stream, and then estimates the number of days during which the in-stream chemical concentration is expected to exceed a COC. PDM counts a day as having an exceedence of a COC if the COC is exceeded for any part of a 24-hour day. As a screening-level model, PDM outputs do not include the duration, location, or aerial extent of exceedences.

Inputs to PDM include facility NPDES number, pretreatment release (i.e., loading rate), post-treatment release, number of release days, and COCs. Because PDM does not contain data for reverse osmosis/desalination facilities, it was necessary to develop hypothetical effluent discharge volumes as discussed below.

2.2 Effluent Discharge Volumes

The size of a reverse osmosis facility is characterized by the design capacity of its daily treated water production. Design capacities for 197 existing reverse osmosis facilities were obtained from an online directory of membrane filtration facilities provided by the American Membrane Technology Association (AMTA). Figure 1 shows the distribution of the design capacities of these facilities in million gallons per day (MGD). The median and mean design capacities are 0.5 MGD and 2.4 MGD, respectively, and the

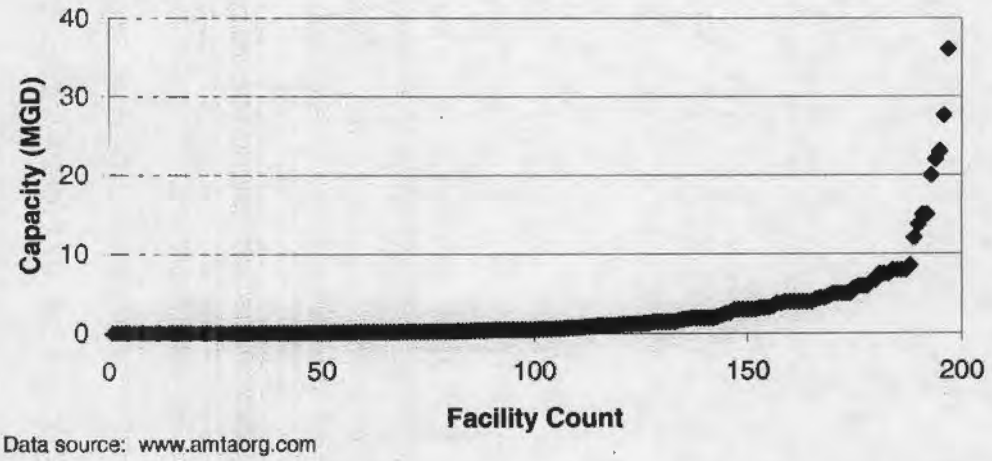
[1] The E-FAST2 model is available from EPA at http://www.epa.gov/opptintr/exposure/pubs/efastdl.htm and documentation is available at http://www.epa.gov/opptintr/exposure/pubs/efast2man.pdf.

largest facility is designed for a daily production of 36 MGD. The 95th percentile of this distribution is approximately 8.5 MGD.

Data on concentrated effluent discharge volumes quantities are not readily available. However, for brackish influent water sources the effluent volume generally amounts to 10 to 25 percent of the influent volume. For seawater desalination, the effluent volume may be as much as 60 percent of the influent volume (AMTA, 2007b).

The descriptive statistics presented above were used to estimate effluent discharge volumes for hypothetical reverse osmosis facilities. Table 1 shows estimates of influent and effluent volumes for hypothetical reverse osmosis seawater desalination plants. For seawater desalination, it was assumed that the wastewater effluent is 60 percent of the raw water influent volume (AMTA, 2007b). As shown in Table 1, this assumption was applied two three facility sizes, corresponding to the maximum, 95th percentile, and mean plant capacities from the data presented in Figure 1. The resulting hypothetical effluent discharge volumes were 53 MGD, 12.75 MGD, and 3.6 MDG. The approach used to estimate hypothetical effluent discharges assumes that the combined volume of the two effluent streams (i.e., potable water and concentrated wastewater) is equal to the influent volume.

Figure 1
Production Capacity of 197 Reverse Osmosis Treatment Plants in the U.S.



Data source: www.amtaorg.com

Table 2 shows effluent discharge volumes for hypothetical reverse osmosis facilities with brackish water influent instead of seawater. The estimates in Table 2 were calculated using the same three facility sizes (i.e., corresponding to the maximum, 95th percentile, and mean plant design capacities) that were used for the estimates in Table 1. However, it was assumed that the concentrated effluent equals 25 percent of the raw water influent volume (AMTA, 2007b). With these assumptions, the effluent discharge volume

from the "maximum" hypothetical brackish water desalination facility (i.e., 12 MGD) is comparable to the effluent discharge volume from the "95th percentile" hypothetical seawater desalination facility (i.e., 12.75 MGD).

Upon comparison of the hypothetical effluent discharge volumes presented in Tables 1 and 2, the three effluent volumes for seawater desalination presented in Table 1 were selected for modeling scenarios for the environmental exposure assessment.

Table 1
Estimated Influent and Effluent Volumes for a Hypothetical Seawater Desalination Facilities[a]

Facility Size	Influent Volume (MGD)	Effluent Volume (MGD)	
		Potable Water	Concentrate
Mean	6	2.4	3.6
95th percentile	21.25	8.5	12.75
Maximum	90	36	53

[a] Calculated assuming the concentrate and potable water effluent streams are 60% and 40%, respectively, of the influent volume.

Table 2
Estimated Influent and Effluent Volumes for a Hypothetical Brackish Water Desalination Facilities[a]

Facility Size	Influent Volume (MGD)	Effluent Volume (MGD)	
		Potable Water	Concentrate
Mean	3.2	2.4	0.8
95th percentile	11.3	8.5	2.8
Maximum	48	36	12

[a] Calculated assuming the concentrate and potable water effluent streams are 25% and 75%, respectively, of the influent volume.

2.3 Receiving Surface Water Flows

Reverse osmosis facility discharges were modeled for 30 river reaches that were identified by EPA during the environmental exposure assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) (Petrie and Montague, 2006). The ADBAC environmental exposure assessment evaluated discharges from steam electric power plants, and the 30 receiving river reaches were associated with actual power plants for which stream flow and effluent discharge data are available in PDM. The 30 facilities were chosen to include a range of receiving reach flows and to include locations distributed throughout the U.S. Table 3 lists the mean and 7Q10[2] stream flows for the 30 river reaches.

Table 3
Effluent Discharge and Stream Flow Data for Modeled Facilities

Facility NPDES Number	Mean Stream Flow (MGD)	7Q10 Stream Flow (MGD)
LA0036145	0.78	0.06
OK0002682	95.91	1.23
TX0054500	5.88	1.55
NM0000108	520.519	1.56
IA0033235	47.81	1.94
WV0005525	33.60	5.94
MI0038172	21.322	6.46
PA0008443	88.90	7.64
MN0000906	462.212	7.64
TX0001163	86.58	10.34
LA0003042	101.33	11.77
SC0001104	964.98	13.27
PA0002062	103.30	13.73
OH0010421	486.089	15.80
IA0000108	521.26	16.19
KS0079057	277.85	18.74
IL0048321	88.85	25.64
PA0002054	473.50	30.37
IN0038806	170.59	35.54
IN0032948	146.03	36.18
NH0001431	296.59	73.02
UT0000116	126.00	82.71
MA0004367	417.42	91.11
IN0041246	279.79	115.66

[2] A 7Q10 stream flow is the lowest seven-day average stream flow over a ten year period.

WA0003280	704.31	213.23
NC0005088	975.75	214.63
GA0004341	1047.42	221.25
FL0025526	401.26	263.63
IL0002186	960.51	308.89
IL0036919	635.87	635.88

[a] If the hypothetical effluent discharge volume was less then the receiving stream 7Q10, the 7Q10 was used as the modeled effluent discharge.

For the BUSAN 1215 reverse osmosis environmental exposure assessment, the 30 river reaches described above were assumed to receive effluent discharges from each of the three hypothetical seawater desalination facilities selected in Section 2.2. However, if the 7Q10 value for a reach was lower than the hypothetical discharge volume, the modeled discharge was assumed to equal the 7Q10 flow.

Reverse osmosis facilities built for desalination are typically located in coastal areas. Because of their locations and because the effluents contain high concentrations of salts and minerals, discharges are expected to be made to the ocean, brackish estuaries, or other tidal water bodies. PDM is not designed to simulate environmental exposures in the ocean or tidal rivers. Therefore, the hypothetical reverse osmosis facilities modeled for this environmental exposure assessment are assumed to discharge to non-tidal rivers.

The number of release days assumed for this analysis was 250. This approach assumes that BUSAN 1215 is not applied on weekends and holidays.

2.4 Monochloramine Concentrations in Effluent

BUSAN 1215 is used in conjunction with sodium hypochlorite (i.e., bleach) to form a family of microbicidal compounds called chloramines. Chloramines are formed when ammonia from the BUSAN 1215 reacts with chlorine from the sodium hypochlorite to produce a mixture of monochloramine (NH_2Cl), dichloramine ($NHCl_2$), or nitrogen trichloride (NCl_3). The relative proportions of these chloramines are determined by the pH of the solution. A detailed discussion of monochloramine chemistry may be found in the environmental exposure assessment of BUSAN 1215 releases from once-through cooling water systems (ICF, 2007). That discussion shows that essentially all of the chloramine formed by the use of BUSAN 1215 according to label instructions will be monochloramine.

Chlorine-based disinfectants, including monochloramine, are typically applied at rates adjusted to oxidative "chlorine demand" of the water to be treated. Application is controlled by monitoring the post-disinfection residual chlorine concentration and not by meeting a prescribed pre-disinfection dose concentration. According to label instructions, which are summarized in Table 4, BUSAN 1215 is to be applied to attain a residual total chlorine concentration of no more than 5 ppm in excess of system oxidant demand. This

concentration was be used to estimate the effluent monochloramine concentration for the environmental assessment.

Table 4
BUSAN 1215 Dosage Information for Industrial Water Systems

Product	Percent Active Ingredient	Label Directions	Application Rate for Analysis
BUSAN 1215	Ammonia 7.59%	When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve total chlorine residual of at least 1 ppm in excess of the system oxidant demand … mix 0.5 fluid ounces BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt).	*Continuous Treatment:* Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. *Intermittent Treatment:* Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours.

Foulant control may be achieved by either an intermittent or a continuous application of BUSAN 1215 and sodium hypochlorite solution. Both methods are intended to achieve a maximum concentration 5 ppm total chlorine in the treated water, and the maximum intermittent application (i.e., 60 minutes every hour) is equivalent to continuous application. Therefore, the maximum continuous application rate was chosen as the application scenario for this analysis.

Total residual chlorine is expected to consist primarily of HOCl, OCl-, and monochloramine, with monochloramine predominating (EPA, 2008). For a conservative, screening-level analysis, it is reasonable to assume that 100 percent of the 5 ppm residual chlorine is present as monochloramine. This assumption is likely to overestimate the actual percentage of monochloramine and, therefore, the concentration of monochloramine. However, the concentration may be underestimated due to the assumption that total residual chlorine does not exceed 5 ppm.

According to the label, sodium metabisulfite may be added to systems treated with BUSAN 1215 to neutralize residual monochloramine. Because neutralization may or may not be performed and may or may not be completely effective at neutralizing

monochloramine, the post neutralization concentration of monochloramine may range from 0 to 100 percent (i.e., 0 ppm to 5 ppm) of the assumed pre-neutralization concentration. For this screening level assessment, it was conservatively assumed that sodium metabisulfite neutralization is not used and that the effluent contains the maximum monochloramine concentration that may be expected from label instructions. Table 5 summarizes the three modeling scenarios developed for the analysis.

Table 5
Modeling Scenarios for Discharges of Monochloramine from Seawater Desalination/Reverse Osmosis Facilities

Scenario Number	Effluent Discharge Volume (MGD)	Concentration of Monochloramine in Effluent (ppm)
1	53	5
2	12.75	5
3	3.6	5

2.5 Monochloramine Concentrations of Concerns (COCs)

Table 6 identifies the seven COCs selected for this analysis. These COCs were obtained from references identified by searching the TOXNET online database.[3] The COCs were selected to include freshwater and marine species and a broad representation of aquatic biota and reported sensitivities. All COCs are from peer-reviewed sources.

[3] The TOXNET database may be accessed at: http://toxnet.nlm.nih.gov/

Table 6
Concentrations of Concern Selected for the Environmental Exposure Assessment of Monochloramine

COC	Test Species	Endpoint Type	Species Habitat	Reference
12 µg/L	*Ceriodaphnia dubia* (Water flea)	LC50	Freshwater	Taylor (1993)
350 µg/L	*Notropis atherinoides* (Emerald shiner)	LC50	Freshwater	Brooks and Seegert (1978)
560 µg/L	*Homarus americanus* (American lobster, stage 1 larvae)	LC50	Marine	Capuzzo et al. (1976)
570 µg/L	*Cynoscion nebulosus* (Spotted seatrout, 10 hr old eggs)	LC50	Esuarine/Marine	Johnson et al. (1977)
650 µg/L	*Ictalurus punctatus* (Channel catfish)	LC50	Freshwater	Brooks and Seegert (1978)
1,230 µg/L	*Lepomis macrochirus* (Bluegill sunfish)	LC50	Freshwater	Brooks and Seegert (1978)
2,030 µg/L	*Gambusia affinis* (Western mosquitofish)	LC50	Freshwater (euryhaline)	Cherry et al. (1982)

3. Estimated Exceedence of Monochloramine COCs in Receiving Surface Waters

Results for Scenarios 1 through 3 are presented in Tables 7 through 9, respectively. Tables 7 through 9 each show the average numbers of days when downstream concentrations of monochloramine were predicted to exceed each of the seven COCs. The average numbers of days were calculated from the modeling results for the 30 individual river reaches. Because the numbers of days with exceedences varied among the river reaches, standard deviations are presented with each of the averages.

Table 7

Number and percent of Days with Downstream Monochloramine Concentrations Exceeding COCs – Scenario 1

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
12	241	23	66%	6%	97%	9%
350	142	66	39%	18%	57%	26%
560	113	64	31%	17%	45%	25%
570	112	63	31%	17%	45%	25%
650	104	62	28%	17%	41%	25%
1,230	65	54	18%	15%	26%	22%
2,030	41	37	11%	10%	17%	15%

Scenario 1: Effluent discharge 53 MGD.

Table 8
Number and percent of Days with Downstream Monochloramine Concentrations Exceeding COCs – Scenario 2

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
12	239	22	65%	6%	96%	9%
350	96	71	26%	19%	38%	28%
560	71	62	19%	17%	28%	25%
570	70	61	19%	17%	28%	25%
650	64	59	17%	16%	26%	23%
1,230	40	45	11%	12%	16%	18%
2,030	26	32	7%	9%	10%	13%

Scenario 2: Effluent discharge 12.75 MGD.

Table 9
Number and percent of Days with Downstream Monochloramine Concentrations Exceeding COCs – Scenario 3

COC (µg/L)	Number of Days With Exceedences		Percent of Days with Exceedences per Year		Percent of Release Days with Exceedences	
	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation	Average Days COC Exceeded	Standard Deviation
12	219	33	60%	9%	87%	13%
350	52	59	14%	16%	21%	24%
560	38	50	11%	14%	15%	20%
570	38	50	10%	14%	15%	20%
650	34	47	9%	13%	14%	19%
1,230	20	32	6%	9%	8%	13%
2,030	13	20	3%	6%	5%	8%

Scenario 3: Effluent discharge 3.6 MGD.

Tables 7 through 9 also present the averages and standard deviations of the percentage of days per year and the percentage of the 250 release days with exceedences of the COCs. Figure 2 compares the percentages of release days with exceedences for the three modeled scenarios.

All three modeled scenarios resulted in exceedence of the lowest monochloramine COC (12 µg/L) on at least 87 percent of the days when BUSAN 1215 was applied. The highest monochloramine COC (2,030 µg/L) was exceeded on at least 5 percent of the days in all modeled scenarios.

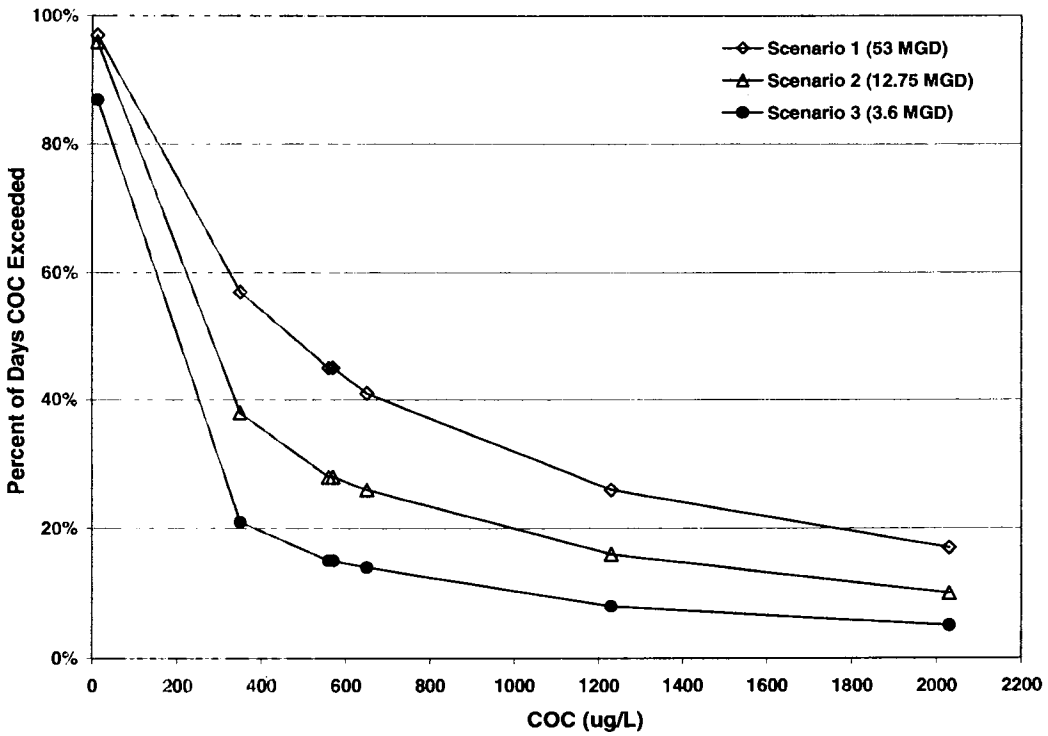
With Scenario 1, in which represents a hypothetical seawater desalination plant with an effluent discharge volume estimated based on the largest identified actual design capacity in the U.S., the average percentage of release day with downstream monochloramine concentrations above COCs ranged from 17 percent for the highest COC (2,030 µg/L) to 97 percent for the lowest COC. With Scenario 3, which is based on the mean design capacity of 197 reverse osmosis facilities in the U.S. the percentage of days with exceedences ranged from 5 percent to 87 percent for the highest and lowest COCs, respectively.

The two lowest COCs are for freshwater species. Large-scale desalination plants generally are located in coastal areas where they would be expected to discharge to marine or estuarine water bodies. The lowest COC for a marine/estuarine species in Table 6 is 560 µg/L, a LD50 for *Homarus americanus* (American lobster larvae). The results

presented in Tables 7 through 9 indicate that this COC would be exceeded on 45%, 28%, and 15% of the release days with Scenarios 1 through 3, respectively.

As shown in Figure 2, the three modeled scenarios resulted in similar relationships between the percentage of days with exceedences and increases in COCs. For the lowest COC, an LD50 for the water flea (*Ceriodaphnia dubia*), the results are not greatly affected by the assumed effluent discharge rates. The results presented in Tables 7 through 9 and Figure 2 all assume the maximum monochloramine concentration and are subject to a number of important limitations discussed in Section 3.

Figure 2
Average Percent of Release Days with Downstream Monochloramine Concentration above COCs



3. Limitations and Uncertainties

This analysis is a screening level evaluation of the potential for discharges from reverse osmosis desalinations facilities to exceed ecotoxicity COCs for monochloramine formed from use of BUSAN 1215. The methodology involves the following potential limitations:

- Reverse osmosis facilities built for desalination are typically located in coastal areas. Because of their locations and because the effluents contain high concentrations of salts and minerals, discharges are expected to be made to the ocean, brackish estuaries, or other tidal water bodies. PDM is not designed to simulate environmental exposures in the ocean or tidal rivers. Therefore, the hypothetical reverse osmosis facilities modeled for this environmental exposure assessment are assumed to discharge to non-tidal rivers.

- The analysis used stream flow data for a sample of 30 river reaches identified for previous EPA environmental exposure assessments. This sample was not necessarily designed to be statistically representative of the national population of receiving surface waters associated with reverse osmosis facilities.

- Monochloramine concentrations in effluent are affected by the pH, temperature, and water chemistry of the water in the reverse osmosis system. All ammonia, chlorine, and monochloramine are assumed to originate with the addition of BUSAN 1215 and sodium hypochlorite. That is, it is assumed that there are no background concentrations of these chemicals in the pre-treatment effluent stream of the receiving surface waters.

- Total residual chlorine is expected to consist primarily of HOCl, OCl-, and monochloramine, with monochloramine predominating (ICF, 2007). This analysis assumes that 100 percent of the total residual chlorine in the effluent is monochloramine.

- The methodology assumes that sodium metabisulfite or other chemicals are not used to neutralize residual monochloramine in the wastewater prior to disposal. It is also assumed that monochloramine does not react (e.g., with suspended organic matter in the receiving water body) between the point of discharge and the point of ecological exposure.

- Effluent discharge volumes were estimated based on the treated water design capacities of 197 reverse osmosis facilities. Because this sample of facilities does not necessarily include all reverse osmosis facilities in operation in the U.S., it is not necessarily representative of the population of actual facilities. In addition, some facilities may produce less than the design capacity, and therefore produce less effluent than estimated based on the design capacities.
- The methodology used to estimate effluent discharge volumes based on treated water capacities, assumes that the combined volumes of treated water and wastewater equal the influent water volume. This methodology also uses assumptions from published sources about the maximum relative proportions of influent and wastewater volumes for seawater and brackish water desalination.

- Because COC exceedences predicted by the PDM do not necessarily occur on consecutive days, the analysis may overestimate the actual potential for ecological

toxicity impacts. The numbers of days with exceedences of COCs have not been compared to the numbers of days of exposure used in the studies from which the COCs were obtained.

- Downstream concentrations of monochloramine are considered to exceed a COC on any given day if the COC is exceeded for any portion of the day. PDM does not identify the duration of the exceedences, and the daily scale results may overestimate the actual potential for monochloramine releases to result in ecological risks.

- The estimated numbers of days with downstream concentrations monochloramine above COCs are average calculated from the results for individual facilities. Facility level results varied considerably, as shown by the standard deviations presented with the averages. Thus, this analysis may under or overestimate the potential for the exceedences at specific facilities.

- The analysis used an assumed release period of 250 days. This assumption is likely to overestimate the number of release days for BUSAN 1215 treatment, especially for initial control. Thus, the results of the analysis may overestimate the number of days with downstream monochloramine concentrations above COCs.

- The release scenarios for the monochloramine analyses were based on the maximum application rate based on product labels. It may be possible to control of target organisms with application rates below the maximum. In addition, continuous dosing was assumed throughout the release period. This assumption may overestimate the daily treatment duration that would be required for effective control.

- For this analysis, effluent discharge rates were assumed to equal the lower of either facility-specific effluent flow rates or the 7Q10 flows of the receiving streams. This approach may over or underestimate average actual effluent discharges.

4. References

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File: My Files\ 2007 Reports\BUSAN 1215\ Environmental Exposure Assessment for Releases of BUSAN 1215 from Seawater Desalination and Reverse Osmosis Systems.

CC: RASSB Chemical File
Siroos Mostaghimi, RASSB

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

Via Federal Express

June 8, 2007

Document Processing Desk (Amend)
US Environmental Protection Agency
OPP, Antimicrobial Division (H7510P), RMB I (PM 31)
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: BUSAN 1215, EPA Reg. No. 14480-433
Label Amend: New uses

Enclosed please find our application to amend the label for the above referenced product to include the addition of a new use pattern: Industrial Water Systems. Enclosed you will find the following information to support this application:

- Completed EPA Form 8570-1.
- Completed EPA Form 8570-34
- Data Requirement Listings (Data Matrix)
- Five (5) Copies of the Proposed Labeling.

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

Fee for Service {811769Q~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 31

Receipt No. S-	811769
EPA File Symbol/Reg. No.	1448-433
Pin-Punch Date:	6/11/2007

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

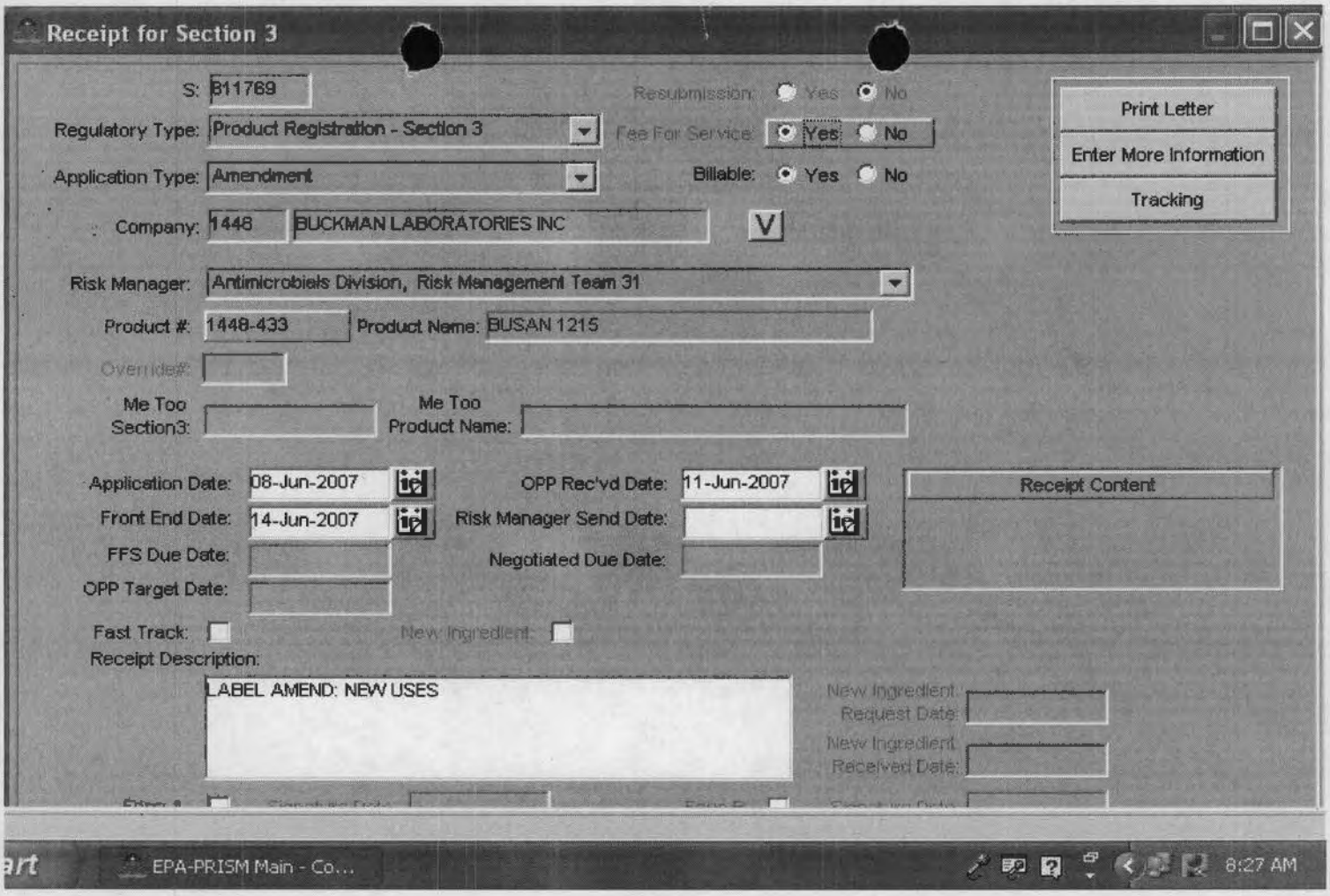
Granted: A50

Amount Due: $ 10,500

Parent/Child Decisions:

Reviewer: Henson / Thompson Date: 6-15-07

Remarks:


Receipt for Section 3
S: 311769
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 1448 BUCKMAN LABORATORIES INC
V
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 1448-433
Product Name: BUSAN 1215
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 08-Jun-2007
OPP Rec'vd Date: 11-Jun-2007
Receipt Content
Front End Date: 14-Jun-2007
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Fast Track:
New Ingredient:
Receipt Description:
LABEL AMEND: NEW USES
New Ingredient Request Date:
New Ingredient Received Date:
EPA-PRISM Main - Co...
8:27 AM

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1448-433	Velma Noble	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
BUSAN 1215	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in reponse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Category: EPA No. A50, CR No. 71 - Action Additional use; non-food; indoor; FIFRA Sec. 2(mm) uses.
[Revision of existing use directions for PULP AND PAPER MILLS; and Addition of New Use: INDUSTRIAL WATER SYSTEMS]
PRIA Fee: $10,500
Contact: cfwatson@buckman.com; Fax (901) 272-6256

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl F. Watson	Sr. Regulatory Toxicologist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Carl F. Watson	Sr. Regulatory Toxicologist
4. Typed Name	**5. Date**
Carl F. Watson	June 8, 2007

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Buckman Laboratories, Inc., 1256 N. McLean Blvd, Memphis, TN 38108 (901) 272-6228	1448- 433
Active Ingredient(s) and/or representative test compound(s) Ammonia (PC Code 5302)	Date June 8, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Industrial, Aquatic, Indoor, Non-food	Product Name BUSAN 1215

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Carl F. Watson	06/08/2007	Carl F. Watson, Ph.D., Sr. Regulatory Toxicologist

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP - 5 2007

Mr. Audrey L. Homes
Regulatory Affairs Specialist, II
Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Subject: Alternate Brand Names Per Notice 98-10
Bulab 6150
EPA Registration Number 1448-433
Notification Application Dated August 3, 2007

Dear Mr. Homes:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

Alternate brand name: (Bulab 6150)

General Comment:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions concerning this letter please contact Drusilla Copeland at (703) 308-6224 or Velma Noble (70) 308-6233

Sincerely,

Velma Nobel
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

Print Form

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Buckman Laboratories, Inc./1448-433	Velma Noble	[x] None [ ] Restricted
4. Company/Product (Name)	PM#	
Buckman Laboratories, Inc./BUSAN 1215	31	

5. Name and Address of Applicant *(Include ZIP Code)*

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Trade Name: Bulab 6150 (see attachment).

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompaning product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Audrey L. Holmes	Regulatory Affairs Specialist, II	901-272-8455

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Audrey L. Holmes	Regulatory Affairs Specialist, II	
4. Typed Name	5. Date	
Audrey L. Holmes	August 3, 2007	

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EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) *Yellow - Applicant Co

Buckman
LABORATORIES

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

via Federal Express

August 3, 2007

Ms. Velma Noble, PM 31
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: BUSAN 1215, EPA Registration Number: 1448-433
Notification of Alternate Trade Name: BULAB 6150

Dear Ms. Noble:

Please find enclosed a Notification of Alternate Trade Name to add the name, BULAB 6150 to the BUSAN 1215 registration (EPA Reg. No. 1448-433). Five (5) copies of the label are enclosed, reflecting the latest EPA stamped label dated March 6, 2007.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

I trust you will find this information satisfactory. If you have any questions or require any additional information, please contact me at (901) 272-8455 or alholmes@buckman.com

Sincerely,

BUCKMAN LABORATORIES INTERNATIONAL, INC.

Audrey L. Holmes
Regulatory Affairs Specialist

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

FQPA

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II
For PRIA Submissions

A	Completed by Product Manager		
PRODUCT REVIEWER: Jennifer Driver		RMB I	TEAM 31
Description of Action: Notification		EPA File Symbol/Reg. No. 1448-433	
Decision No. 383171	Submission No. 815819	Fee for Service Action Code:	
FQPA Action Code: 332	Non-FQPA Action Code:	Fee for Service Fee: $	

APPLICATION DATE	8	3	2006
EPA PIN DATE	8	6	2006
REVIEWER ASSIGNED DATE			2006
DATE DUE FROM SCIENCE			
DATE DUE TO PM			
DATE DUE OUT OF AGENCY			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure

COMMENTS: NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.
Notification - Send to Driver

ATTACHMENTS: LABELING

B	For Arctic Slope Contract Only		
Contractor: Arctic Slope		Contract No.:	ARCTIC SLOPE/MANAGER
Draft Task: Signature _____ _____ (Est. hrs)		Final Task: Signature _____ _____ (Total hrs)	

C	Reviewer's Comments:

DATE FEE PAID: | RESPONSE CODE: _____ RESPONSE DATE: